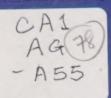


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2011



Report of the
Auditor General
of Canada
to the House of Commons

FALL

Chapter 1
Canada's Economic Action Plan





2011



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Office of the Auditor General of Canada

The Fall 2011 Report of the Auditor General of Canada comprises Matters of Special Importance, Main Points—Chapters 1 to 5, Appendices, and five chapters. The main table of contents for the Report is found at the end of this publication.

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Chapter

1

Canada's Economic Action Plan

Performance audit reports

This report presents the results of a performance audit conducted by the Office of the Auditor General of Canada under the authority of the Auditor General Act.

A performance audit is an independent, objective, and systematic assessment of how well government is managing its activities, responsibilities, and resources. Audit topics are selected based on their significance. While the Office may comment on policy implementation in a performance audit, it does not comment on the merits of a policy.

Performance audits are planned, performed, and reported in accordance with professional auditing standards and Office policies. They are conducted by qualified auditors who

- establish audit objectives and criteria for the assessment of performance;
- gather the evidence necessary to assess performance against the criteria;
- report both positive and negative findings;
- · conclude against the established audit objectives; and
- make recommendations for improvement when there are significant differences between criteria and assessed performance.

Performance audits contribute to a public service that is ethical and effective and a government that is accountable to Parliament and Canadians.

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Canada's Economic Action Plan

Main Points

What we examined

In January 2009, the Government of Canada launched its Economic Action Plan to stimulate the economy in response to the global economic downturn. This stimulus plan represented about \$47 billion in federal spending and an additional \$14 billion funded by provinces and territories. Its purpose was to create jobs, build infrastructure, accelerate housing construction, stimulate spending by Canadians, and support businesses and communities. Budget 2009 also contained measures to add stability to the financial sector, which sought to improve access to financing for consumers and business by providing up to \$200 billion in credit.

Our first audit of the Economic Action Plan, reported in October 2010, examined program design and delivery mechanisms put in place by selected federal departments and agencies to implement the Economic Action Plan.

Our second audit of the Economic Action Plan is the subject of this chapter. The audit looked at three programs with a total dollar value of \$7 billion. The \$4 billion Infrastructure Stimulus Fund targeted provincial, territorial, and municipal construction-ready projects to build or rehabilitate infrastructure. The \$2 billion Knowledge Infrastructure Program targeted post-secondary institutions across Canada for new construction, deferred maintenance, repair, and expansion of projects to improve the quality of research and development and deliver advanced knowledge and skills training. The \$1 billion Community Adjustment Fund was established to create or maintain jobs and support businesses in communities hit hard by the economic downturn.

Our audit included two departments and five regional development agencies that distributed funds under the programs. We examined whether they had monitored and reported on program spending and results.

During our audit, the government extended the completion deadline for many projects from 31 March 2011 to 31 October 2011. This chapter is a report on selected programs up to 31 March 2011, the date when our audit work was substantially completed. It is not a report on the final results of the Economic Action Plan.

Why it's important

Given the short time frame planned for the Economic Action Plan, as well as the large amounts of public money involved, it was important that the government mitigate risks through appropriate monitoring of programs at every stage, timely tracking and reporting of costs, adherence to its own Policy on Transfer Payments, and reliable reporting of results.

A key risk for the government was that its measures would fail to quickly stimulate the Canadian economy. That was the reason for giving priority to projects that were "construction ready" and requiring that projects be completed by 31 March 2011, to support the government's assertion that stimulus measures would be targeted. timely, and temporary.

What we found

- · For the three Economic Action Plan programs we audited, the federal government monitored the progress and spending of projects, permitting it to take corrective action in a number of cases. Progress on many projects was slower than initially expected. Departments and agencies delivering the three programs that we audited reported that 4,070 out of 5,845 projects (70 percent) were completed by the 31 March 2011 deadline. Following the federal government's announcement of a deadline extension, almost one third of projects in the two largest programs we examined were granted an extension to 31 October 2011. The decision to extend the time frames of these programs was supported by an analysis conducted by the Privy Council Office and the Department of Finance Canada.
- Spending figures provided by the departments and agencies as of 31 March 2011 indicate that the three programs had largely achieved the Economic Action Plan objective to spend federal resources within a two-year time frame. However, total federal spending for all three programs will not be known until projects submit final claims and close-out reports to the federal entities.
- · Although a key objective of the Community Adjustment Fund was to create and maintain jobs in communities hit hard by the economic downturn, the design of the program did not allow for performance measurement and reporting against this key objective.

· Infrastructure Canada, Industry Canada, and the regional development agencies reported performance information on their Economic Action Plan programs in various places throughout their departmental performance reports. In our view, this fragmented presentation makes it difficult for parliamentarians and Canadians to obtain an overall picture of results achieved against planned performance expectations and public resources spent.

The entities have responded. The entities agree with our recommendations. Their detailed responses follow each recommendation throughout the chapter.

Introduction

Background

- 1.1 In January 2009, the federal government introduced a budget to mitigate the effects of the severe global economic crisis. The downturn was causing significant job losses in key sectors, such as construction and forestry. Budget 2009 was named "Canada's Economic Action Plan." It was intended to stimulate the economy partly through increases in government funding for public projects. The plan was designed to build infrastructure, stimulate housing construction and spending by Canadians, and support businesses and communities. The time frame set for the plan was two years. The deadline for completion was 31 March 2011 for the vast majority of initiatives.
- Over 35 federal departments and agencies worked to deliver almost 90 programs, including infrastructure programs, in support of the Economic Action Plan. The initiatives involved funding of about \$47 billion, with an additional \$14 billion funded by the provinces and territories. The plan also provided up to \$200 billion in credit to improve access to financing for consumers and businesses. The plan was based on three guiding principles: that the stimulus should be timely, targeted, and temporary.
- As a large and complex initiative, the Economic Action Plan significantly increased workload in federal departments and agencies. Programs were coordinated and delivered through provinces, territories, municipalities, third parties, non-governmental organizations, and the private sector. Since speed of delivery was crucial, officials were under pressure to quickly design, deliver, monitor, and report on new or accelerated federal programs, while continuing to deliver existing programs.

Previous audit work

We first examined the 2009 federal stimulus measures in the 2010 Fall Report of the Auditor General of Canada, Chapter 1, Canada's Economic Action Plan. We audited 11 of the Economic Action Plan programs through the design and implementation stages. We examined program design and delivery, eligibility, the roles of internal audit and central agencies, and compliance with financial management and environmental requirements.

1.5 To inject \$47 billion of stimulus funding into the economy within a two-year time frame, the government found it necessary to rely on applicants' attestations that their projects were ready to proceed and could be completed by the deadline of 31 March 2011. We found that some projects were delayed and that, because the government made project approval decisions on the basis of limited information, it had accepted the risk that some projects would not meet the deadline. In April 2010, we completed our audit work for the chapter included in the 2010 Fall Report. At that time, projects were in the early stages of implementation, many project files did not contain payment claims or progress reports, and it was not known how many projects would be at risk of missing the deadline.

Programs selected for examination

- 1.6 For this second audit, we examined selected Economic Action Plan programs as they were being delivered and completed. We selected three programs that delivered stimulus in the form of thousands of projects across the country: the Infrastructure Stimulus Fund, administered by Infrastructure Canada; the Knowledge Infrastructure Program, administered by Industry Canada; and the Community Adjustment Fund, administered by five of the federal government's regional development agencies and Industry Canada (Exhibit 1.1).
- 1.7 The Economic Action Plan allotted \$4 billion to the Infrastructure Stimulus Fund. This program provided short-term funding for construction-ready projects to rehabilitate provincial, territorial, and municipal existing assets and new infrastructure. Funding was intended to rehabilitate wastewater systems, public transit, highways, roads, parks, trails, and municipal buildings.
- 1.8 The Economic Action Plan also allotted \$2 billion to the Knowledge Infrastructure Program. It supported short-term infrastructure enhancement at post-secondary institutions across Canada, including universities, colleges, and publicly funded polytechnic schools and institutes of technology. Funding was intended to support new construction and deferred maintenance, repair, and expansion projects aimed at improving research and development quality and the ability to deliver advanced knowledge and skills training.
- 1.9 The Community Adjustment Fund was allotted \$1 billion to support activities such as community transition plans that fostered economic development, science and technology initiatives, and other short-term measures promoting economic diversification.

Funding targeted communities that had fewer than 250,000 residents, had suffered major layoffs, and lacked alternative employment opportunities or had experienced a year-over-year increase of 20 percent or more in Employment Insurance claimants. A primary objective was to maintain existing jobs or create new ones.

1.10 Recipients of funding under these Economic Action Plan programs had to meet several conditions, including requirements to complete their projects by 31 March 2011 and to report quarterly on project progress.

Exhibit 1.1 Federal entities and Economic Action Plan programs examined in our second audit

Responsible organizations	Audit scope	Number of approved projects and total program allocation
Infrastructure Canada	Infrastructure Stimulus Fund	4,128 projects
		• \$4 billion
Industry Canada	Knowledge Infrastructure Program	538 projects
	Community Adjustment Fund, delivered through Federal Economic Development Initiative for Northern Ontario*	\$2 billion
Regional development agencies:	Community Adjustment Fund	1,179 projects
Atlantic Canada Opportunities Agency		\$1 billion
Canadian Northern Economic Development Agency		
Economic Development Agency of Canada for the Regions of Quebec		
Federal Economic Development Agency for Southern Ontario		~
Western Economic Diversification Canada		
Central agencies:	Reporting to Parliament	
Treasury Board of Canada Secretariat	Extending deadline of selected	
Department of Finance Canada	programs	
Privy Council Office		

^{*} The total allocation and number of approved projects for the Community Adjustment Fund delivered by the Federal Economic Development Initiative for Northern Ontario are included in the Community Adjustment Fund totals.

Contribution—Conditional transfer payments to an individual or organization for a specified purpose. These payments are pursuant to a contribution agreement, and are subject to being accounted for and audited.

Transfer payment—A monetary payment or a transfer of goods, services, or assets to a third party. One type of transfer payment is a contribution. Transfer payment programs are major commitments of federal government resources and key instruments for the government to further its broad policy objectives and priorities. Cabinet determines when a transfer payment program is the most appropriate policy instrument, and which objectives and outcomes are to be achieved by means of the transfer payments.

- 1.11 For the programs we audited, the federal government transferred its funding in the form of contributions. Unlike a grant, the recipient of a contribution must give the government an accounting of how it spent the money and what results it achieved.
- 1.12 The Infrastructure Stimulus Fund and the Knowledge Infrastructure Program transferred federal funding to the provinces and territories, as well as to a small number of direct funding recipients, including cities, ports, and educational institutions. In most cases, the provinces and territories were responsible for monitoring project status, verifying claims for payment, and submitting quarterly financial and progress reports to the federal department concerned. For the few agreements that did not involve a provincial or territorial government, Infrastructure Canada and Industry Canada were responsible for directly monitoring progress and reviewing claims for eligibility.
- 1.13 Most federal funding under the Community Adjustment Fund was transferred directly to individual project recipients through contribution agreements administered by five federal regional development agencies and, in the case of one region, Industry Canada. The project recipients were required to report quarterly on project spending and progress, and generally to submit claims to the responsible department or regional development agency.
- 1.14 On 2 December 2010, during the planning of this audit, the government announced that a small percentage of Economic Action Plan projects had been delayed and were at risk of missing the 31 March 2011 deadline. The government therefore extended the funding and completion deadline for certain Economic Action Plan programs by a full construction season to 31 October 2011. This formal extension applied to two programs in our audit scope: the Infrastructure Stimulus Fund and the Knowledge Infrastructure Program.

Focus of the audit

1.15 We audited the Infrastructure Stimulus Fund, the Knowledge Infrastructure Program, and the Community Adjustment Fund, which had a combined total dollar value of \$7 billion. The audit findings cannot be extended to other Economic Action Plan programs. Our focus was on how the federal government accounted to Parliament and Canadians by monitoring project progress, accounting for money spent, and reporting on the significant public resources allocated under the Economic Action Plan. We did not audit the recipients of Economic Action Plan projects or the value received by them as a

result of spending under the Plan. Specifically, the audit examined whether selected federal departments and agencies had

- monitored progress, including whether projects were being completed as intended, and took corrective action where necessary;
- monitored federal spending for selected Economic Action Plan programs; and
- reported to Parliament, through departmental performance reports, on progress and actual spending for selected programs.
- 1.16 As part of our examination of monitoring, our audit also looked at the role of central agencies in the decision to extend the project deadline.
- 1.17 In December 2010, Infrastructure Canada and Industry Canada approved new short-term projects, using funds redirected from projects that had been approved earlier but that could not be spent by the deadline of 31 March 2011. One purpose of approving new projects was to minimize the possibility that unspent funding would lapse. To be eligible, the new projects had to be completed by 31 March 2011. We examined a number of the new projects to confirm their eligibility.
- 1.18 For this second audit of the Economic Action Plan, we examined projects that were subject to the original deadline of 31 March 2011 as well as the extended deadline of 31 October 2011. While we were performing the audit, thousands of projects across the country were being completed or had been granted an extension. Given the timing of the audit and the date set for submitting final close-out reports on Economic Action Plan projects, final results were not always available.
- 1.19 For projects completed by 31 March 2011, most funding recipients were required to submit final close-out documentation within 90 days of that date. Since a large number of Infrastructure Stimulus Fund projects were expected to be completed close to 31 March 2011, Infrastructure Canada gave recipients the option to submit final reports by 30 September 2011. For all Infrastructure Stimulus Fund and Knowledge Infrastructure Program projects extended to 31 October 2011, recipients were required to submit final close-out documentation within 90 days of the deadline, that is, by 31 January 2012. Until final claims and close-out project reports are submitted, departments and agencies will not be able to confirm the total federal spending and final project results.

1.20 More details about the audit objectives, scope, approach, and criteria are in About the Audit at the end of this chapter.

Observations and Recommendations

requirement to be completed by 31 March 2011.

Monitoring progress and spending

Being completed as intended—Refers to projects that are progressing in accordance with the scope set out in the original application approved by the federal government.

Corrective action—Refers to action that may involve withholding federal funds, changing the project scope, raising the risk rating, increasing monitoring or communications with the recipient, extending the project deadline, transferring the project to another program, or cancelling the project.

- 1.21 In our second audit of the Economic Action Plan, we looked at the processes put in place by federal departments and agencies to monitor the progress of projects and track government spending. We looked at the number of projects that met the original deadline and the amount of federal funding spent as of 31 March 2011. Federal accountability policies require departments and agencies to monitor project progress and federal spending, to confirm whether projects are being completed as intended, and to take corrective action as necessary. We also looked for evidence that projects approved near the end of the Economic Action Plan met eligibility criteria, including the
- 1.22 The Treasury Board of Canada Secretariat's Directive on Transfer Payments requires departments and agencies to demonstrate accountability, transparency, and effective control in the management of transfer payments, such as contributions. Federal program managers are required to exercise due diligence in tracking the use of public resources; this includes monitoring how funds are spent and to what effect. The Directive on Transfer Payments states that departments and agencies should respect the jurisdiction of provincial or territorial governments. It is the duty of the federal government to have accountability mechanisms in place that allow for appropriate and timely monitoring and reporting on the use of the funds provided and the results achieved.
- 1.23 In view of the short time frame of the Economic Action Plan as well as the large amount of public money involved, it was important for the government to mitigate risks through appropriate monitoring at every stage, and to ensure timely tracking of progress and spending. Monitoring of federal spending was also important because a key risk facing the government was the possible failure of recipients to complete projects and spend federal funding by the deadline of 31 March 2011. If that happened, the Economic Action Plan might fall short of its objective of stimulating the economy in a timely manner.
- 1.24 We reviewed the systems and practices used by departments and agencies to monitor overall progress and spending. We also reviewed a representative sample of projects funded under the Infrastructure

Stimulus Fund, the Knowledge Infrastructure Program, and the Community Adjustment Fund. Finally, we conducted site visits to selected projects.

Infrastructure Canada used a risk-based approach to monitor Infrastructure Stimulus Fund projects

1.25 The Infrastructure Stimulus Fund was the largest Economic Action Plan infrastructure program. Under this program, Infrastructure Canada approved funding for over 4,000 projects in all provinces and territories (Exhibit 1.2). Provinces, territories, and some large municipalities managed most of the projects. They were responsible for monitoring project status, verifying the eligibility of claims, and submitting claim and progress reports every three months for projects scheduled to end by 31 March 2011. The Department also conducted its own monitoring activities. In the case of projects that were extended to 31 October 2011, progress reports were required every two months.

Exhibit 1.2 The Infrastructure Stimulus Fund supported public infrastructure projects

Highway resurfacing, Burlington, Ontario

The Infrastructure Stimulus Fund provided \$4.15 million for a project to replace a stretch of a major highway in Burlington, Ontario. The aim was to advance the highway's restoration and extend its structural life.



1.26 The Treasury Board Policy on Transfer Payments requires that monitoring and reporting reflect the risks specific to a program and the recipient's risk profile. Consistent with the policy, we found that Infrastructure Canada adopted a risk-based approach to monitoring Infrastructure Stimulus Fund projects and that it established a process including controls at the beginning and end of the program. For example, the Department initially assessed risk for every project and then used the information provided by its funding partners to reassess project risk every quarter. When the Department deemed corrective action to be appropriate, it enhanced monitoring for projects and redirected funding to new projects from others that were delayed, under budget, or cancelled. For medium- and high-risk projects, Infrastructure Canada held meetings twice a year. It also conducted site visits for high-risk projects.

- 1.27 Under the monitoring approach used by Infrastructure Canada, provinces and territories submitted claim and progress reports containing information such as key project dates, elapsed time, and percentage of project completion. Using this data, as well as information obtained through its monitoring activities, Infrastructure Canada performed analyses to monitor project progress. For most medium- and low-risk projects, the Department relied primarily on the monitoring performed by its funding partners to obtain assurance that projects were being completed as intended.
- 1.28 To assess the risks of relying on funding partners for project management, Infrastructure Canada conducted compliance audits. These tested whether partners had adequate controls, processes, and practices to ensure that recipients complied with the terms and conditions of their contribution agreements. The audits were carried out in provinces, territories, and two major urban centres midway through the two-year delivery schedule for the Infrastructure Stimulus Fund. According to Infrastructure Canada officials, the assurances provided by these audits confirmed that funding partners had sufficient controls in place and were in compliance with the terms of their contribution agreements. We did not audit the compliance audits.
- 1.29 Provinces and territories reviewed funding recipients' invoices to check eligibility and reimburse costs, and then submitted quarterly claim and progress reports to Infrastructure Canada to recover these costs. We observed that there could be a considerable lag between the time of construction activity and the date when a claim was submitted to Infrastructure Canada for reimbursement. To comply with the contribution agreement requirement for quarterly reporting, provinces and territories often submitted only a progress report, with a zero-dollar claim. Sometimes they did not seek reimbursement of costs incurred until a project was close to completion. This practice did not always provide the Department with current information on project costs incurred, but it allowed funding partners (mainly provinces) to cashmanage their infrastructure projects.
- 1.30 We found that Infrastructure Canada met its requirement to monitor the spending of federal funds. The Department used a risk-based approach in the review of claims submitted by recipients. The total federal contribution is capped; that is, it cannot exceed the maximum amount allocated to the program. As of 31 March 2011, the Department reported to us that it had paid out approximately \$1.7 billion and had received information that an additional \$1.1 billion in costs had been estimated to have been incurred by projects. Some \$1.2 billion or 30 percent of the funding remained to be spent.

- 1.31 Infrastructure Canada required a final completion report for each project, including an attestation by a certified professional that the project had been completed as intended. According to preliminary information from the Department, approximately two thirds of 4,128 Infrastructure Stimulus Fund projects were completed as of 31 March 2011. The Department also required a final financial report for each project to confirm the amount of federal funding spent and the eligibility of all costs claimed. Final reports for projects completed by 31 March 2011 are due in late September 2011, and in January 2012 for projects granted an extension to 31 October 2011.
- 1.32 On 20 December 2010, near the end of the two-year period of the Economic Action Plan, Infrastructure Canada approved 42 additional projects on the condition that they be completed by 31 March 2011. It funded these Infrastructure Stimulus Fund projects using funds from other projects that had been completed under budget or cancelled. We looked at a sample of these projects and confirmed that they met eligibility criteria. Of the 42 additional projects, 34 opted to take advantage of the extension to 31 October 2011.

Additional controls gave Industry Canada increased assurances on Knowledge Infrastructure Program projects

- 1.33 Under its Knowledge Infrastructure Program, Industry Canada approved 538 projects for deferred maintenance, repair, and expansion at colleges and universities (Exhibit 1.3). The contribution agreements for most of these projects gave the provinces and territories responsibility for monitoring them and reviewing the eligibility of claims. The Department further required provinces and territories, as well as direct recipients, to submit progress reports every three months for each project, with information on work performed and outstanding, costs incurred, and whether the project was on track to be completed by 31 March 2011. For projects that had been granted extensions to 31 October 2011, the Department required progress reports every two months.
- 1.34 We found that Industry Canada monitored the progress of projects, tracked federal spending and results, and took corrective action when projects were falling behind schedule. To meet its accountability requirements for the use of funds and results achieved under the Knowledge Infrastructure Program, Industry Canada put a number of controls in place. These provided key information to the

Department on project progress and federal spending. They also helped to manage program risks, including the risk that projects would not meet the 31 March 2011 deadline.

Exhibit 1.3 The Knowledge Infrastructure Program supported projects at academic institutions

New ventilation system, Mount Allison University, New Brunswick

Industry Canada's Knowledge Infrastructure Program provided \$1.2 million to Mount Allison University in Sackville, New Brunswick, for a project to install new exhaust fans and fume hoods in its chemistry building. The equipment replaced an outdated ventilation system. The funding recipients told us that the project had been a top priority of the university for over 10 years. The new system was



designed to provide additional workspaces and cleaner air for professors and students, and was expected to lead to more opportunities for performing experiments and contributing to research.

- 1.35 One of the controls was the design of the Knowledge Infrastructure Program's payment schedule. Industry Canada established a regular schedule for payments over the two-year time frame, and required projects within the provinces and territories to demonstrate satisfactory progress before it would release a payment. This requirement gave Industry Canada the information it needed to determine whether projects were on track to meet the 31 March 2011 deadline and whether spending was on target.
- 1.36 Another control measure was the hiring of an accounting firm, with qualified infrastructure specialists on staff, to review and analyze quarterly progress and spending reports from the recipients. The reports provided information on total costs incurred, which enabled the Department to track the progress of projects against expected spending and to identify high-risk projects. Particular attention was paid to assessing the progress of projects with a high dollar value. The Department then used this information to determine whether it should make a regular quarterly payment or take corrective action by holding back funding to a province or territory if construction progress was behind schedule.
- 1.37 We found that the requirement to demonstrate satisfactory progress before release of a payment resulted in the frequent submission of progress reports on Knowledge Infrastructure Program projects. The reports described the work performed and often included photographs. The information thus gathered, together with the

payment schedule, gave the Department increased assurance that projects were being completed as intended and that the federal Knowledge Infrastructure Program would stimulate the economy within the two-year time frame.

- 1.38 The accounting firm conducted site visits and compliance audits of selected projects, and reported to Industry Canada on whether incurred costs were eligible for reimbursement and whether funds were being used as intended. The firm also performed technical reviews of some high-risk projects to determine whether they would be able to meet the deadline for completion. For projects involving a direct agreement between Industry Canada and the recipient, the firm performed site visits for the purpose of confirming whether milestones were being met and funds were being used for their intended purpose. We did not audit the work undertaken by the accounting firm.
- completion report for each project and an attestation by a certified professional that the project had been completed as intended. Preliminary information indicated that approximately two thirds of 538 Knowledge Infrastructure Program projects were completed by 31 March 2011. Industry Canada reported to us that as of this date, it had spent 88 percent of the \$2 billion allocated for the Knowledge Infrastructure Program as set out in the payment schedule with the provinces and territories. The Department will confirm total federal spending for the program as well as eligibility of costs through project close-out reports and financial audits. The Department largely achieved the Economic Action Plan objective of spending federal funding within the two-year time frame.
- 1.40 Like Infrastructure Canada, Industry Canada approved additional projects near the end of the two-year period of the Economic Action Plan. We found that all of these projects met eligibility criteria. The Department reported that all new Knowledge Infrastructure Program projects were completed by 31 March 2011.

Industry Canada and regional agencies monitored Community Adjustment Fund projects

1.41 Five regional development agencies and Industry Canada were responsible for delivering the Community Adjustment Fund. They approved a total of 1,179 projects that were intended to support economic development and create or maintain jobs in communities hit hard by the economic downturn (Exhibit 1.4).

Exhibit 1.4 The Community Adjustment Fund supported projects in communities hit hard by the economic downturn

New industrial incubator, Drummondville, Quebec

The Community Adjustment Fund provided \$500,000 to the Drummondville Economic Development Authority to build a multi-sector industrial incubator. The facility was designed to provide affordable and flexible rental arrangements, as well as shared administrative support and



mentoring for up to seven firms. The project aimed to create new construction jobs. The incubator is expected to help the local community by generating longer-term employment and related economic benefits. Without federal assistance, the Authority told us that it could not have undertaken the project at this time and that some of the new businesses would not be operating.

Forestry and wildlife project, Cranbrook, British Columbia

The Community Adjustment Fund provided approximately \$900,000 for a project to restore grasslands in Cranbrook. This small B.C. community depended heavily on forestry and was severely affected when the economic downturn led to the shutdown of many local sawmills. The project was intended to provide employment, reduce the likelihood of forest fires, and restore ecosystems that are home to multiple endangered species.



- 1.42 We found that regional development agencies and Industry Canada tracked the progress of Community Adjustment Fund projects, monitored their use of federal funding, confirmed whether projects were being completed as intended, and took corrective action when necessary. However, we noted variations in the frequency of monitoring on the part of regional development agencies and Industry Canada. This affected the quality of information available to assess project progress, as well as the ability to determine whether projects were being completed as intended.
- 1.43 For the projects that we reviewed, Western Economic Diversification Canada required recipients to report quarterly on progress against project milestones. It then actively monitored progress against those milestones and took corrective action when necessary. It also conducted a detailed review of the projects' claims. This approach to monitoring helped identify whether projects were being completed on time and as intended.
- 1.44 We found that contribution agreements of the Economic Development Agency of Canada for the Regions of Quebec, the Atlantic Canada Opportunities Agency, and the Canadian Northern

Economic Development Agency did not include a requirement that recipients report quarterly on the progress of projects despite the terms and conditions of the Community Adjustment Fund program. We looked at project files from the Economic Development Agency of Canada for the Regions of Quebec and the Atlantic Canada Opportunities Agency. While those agencies did not make quarterly reporting a requirement, we found that they still collected updates on progress and spending for the projects that we reviewed and took corrective action when needed. The agencies could request progress reporting, but this often involved informal and ongoing communication with project recipients, many of whom had an established relationship with the agency responsible. The progress information provided agencies with increased assurance that projects were being completed on time and as intended.

- 1.45 In its contribution agreements, the Federal Economic Development Agency for Southern Ontario required recipients to report monthly against milestones. However, for the projects we examined, we found that the Agency did not always enforce this reporting requirement. It often did not monitor or verify project status until a project was nearly or already completed. As a result, the Agency did not know whether some projects were being completed as intended until near or after completion of those projects.
- 1.46 We also found that approximately one third of Community Adjustment Fund projects in Southern Ontario did not meet completion deadlines. Two-year funding was not available for projects in this region, as the Federal Economic Development Agency for Southern Ontario was in the process of being created when the Community Adjustment Fund was announced. As a result, projects went through two separate project application and approval processes and were funded for one year only. Officials told us that the one-year time frame affected the number of projects that were completed on time.
- 1.47 Most regional development agencies and Industry Canada required recipients to submit claims for the costs incurred on their projects. We reviewed projects from Western Economic Diversification Canada, the Atlantic Canada Opportunities Agency, the Federal Economic Development Agency for Southern Ontario, and the Economic Development Agency of Canada for the Regions of Quebec. We found that these agencies reviewed claims and confirmed that costs were eligible before releasing a payment. The review provided the agencies with the information they required to ensure that recipients were reimbursed only for work that had been performed and was eligible under the program.

1.48 Preliminary information indicated that approximately 90 percent of 1,179 Community Adjustment Fund projects were completed by 31 March 2011. The regional development agencies and Industry Canada reported to us that, out of the \$1 billion allocated to the Community Adjustment Fund, they had paid out approximately \$739 million and had received information that additional costs of \$142 million had been incurred by projects as of 31 March 2011. This means that the regional development agencies and Industry Canada spent most (88 percent) of their federal funding within the two-year time frame.

Analysis supported the decision to extend project deadlines

- 1.49 Funding under Canada's Economic Action Plan was designed to provide timely, targeted, and temporary stimulus to the Canadian economy in order to ensure that the government's fiscal position was structurally sound and to support the recovery. In Budget 2009, the government stated that the budget measures were intended to have an impact on the economy in the short term and that unspent stimulus funds would not be carried forward beyond the end of the 2010–11 fiscal year.
- Throughout 2009 and 2010, federal monitoring information suggested that projects were progressing more slowly than expected and the federal government was under increasing pressure to reconsider the 31 March 2011 deadline. Parliamentarians and the Federation of Canadian Municipalities, among others, called on the government to show flexibility and allow more time for projects at risk of missing the deadline. In an appearance before the House of Commons Standing Committee on Government Operations and Estimates, the Federation noted considerable delays in getting projects approved and contribution agreements signed; the result, in many cases, was a late start on work scheduled to begin during the construction season in the first year of the Economic Action Plan. In May 2010, the Standing Committee issued an interim report on implementation of the Economic Action Plan. The report recommended that the federal government honour its funding commitments for all Economic Action Plan projects that had been approved for stimulus spending, even if they would not be completed by 31 March 2011.
- 1.51 In September 2010, the government responded to the interim report of the Standing Committee. It stated that federal officials were working with their counterparts across the country to ensure completion of projects by 31 March 2011. Furthermore, in Canada's Economic Action Plan, Year 2: A Sixth Report to Canadians

(September 2010), the government stated that projects were on track to meet the deadline. Despite these assertions and the corrective action taken by departments and agencies to mitigate the risk of missing the deadline, the federal government continued to receive requests for an extension late into 2010.

- 1.52 On 2 December 2010, the Prime Minister announced that the government would extend the funding deadline by a full construction season to 31 October 2011 for four Economic Action Plan infrastructure programs, including the Infrastructure Stimulus Fund and the Knowledge Infrastructure Program. The Prime Minister stated: "Nearly 90 percent of infrastructure projects will be done by the . . . deadline [31 March 2011] we set out."
- 1.53 We examined the role of the Privy Council Office and the Department of Finance Canada in the decision to offer extensions to 31 October 2011 for selected Economic Action Plan infrastructure programs. We also looked at the number of infrastructure projects given an extension under the Infrastructure Stimulus Fund and the Knowledge Infrastructure Program. Finally, we considered how the government dealt with Community Adjustment Fund projects that did not meet the 31 March 2011 deadline.
- 1.54 The implementation of Canada's Economic Action Plan was a priority of the Privy Council Office and the Department of Finance Canada. We looked for evidence that these central agencies conducted an analysis of the status of projects and the state of the economy in support of discussions on whether to extend the project completion deadline for selected infrastructure programs.
- 1.55 An informed analysis was important because the Economic Action Plan was intended to inject stimulus into the economy, when necessary, and withdraw it as the recovery gained a solid footing. We looked for evidence that central agencies used data from federal departments and agencies on the status of Economic Action Plan projects. We also examined whether the government considered the risks of stopping federal funding, as well as the risks of extending the deadline to the recovery of the economy and to the completion of projects that were largely finished.
- 1.56 We found that, in October and November 2010, central agencies requested regular project status updates and analyses from Infrastructure Canada and Industry Canada, assessing the potential amount of federal funds that would not be spent by 31 March 2011. Federal officials maintained that the vast majority of projects would be completed

- on time. They were nevertheless aware of a lag between construction activities on the ground and reporting of the completed activities; this made it difficult to assess precisely the progress of projects.
- 1.57 We found that the decision to extend the 31 March 2011 deadline for projects under the Infrastructure Stimulus Fund and the Knowledge Infrastructure Program was based on a central agency analysis of information supplied by departments and agencies on the progress of projects. We also found that the analysis assessed the risk of discontinuing federal funding before Economic Action Plan investments could be realized.
- 1.58 Furthermore, the central agency analysis considered the strength of the economic recovery in Canada and globally. The analysis concluded that the weak global economic situation at the time could jeopardize the recovery in Canada and that continued federal support for Economic Action Plan projects beyond the original deadline was appropriate. In 2010, the economy was in a much more fragile state than had been expected when the Economic Action Plan was launched. The economic environment was not the principal factor considered in the decision to change the deadline, but it afforded the government the flexibility to extend delayed projects.
- 1.59 Infrastructure Canada and Industry Canada reported that 1,433 Infrastructure Stimulus Fund projects and 189 Knowledge Infrastructure Program projects were given an extension to 31 October 2011. This represented approximately one third of projects in the two programs. The number of extended projects was higher than the government had estimated. However, since the extension was offered to all recipients able to satisfy new conditions, it was not possible to determine conclusively how many projects that opted for an extension would have been able to meet the original deadline.
- 1.60 The extension was not offered to Community Adjustment Fund projects. According to central agency officials, the original deadline was maintained because regional development agency officials had reported that the vast majority of projects were on track to be completed, as scheduled, by 31 March 2011. When some projects were in fact delayed, the agencies, communities, and recipients requested a similar extension.
- 1.61 Regional development agency officials and Industry Canada reported that 10 percent of Community Adjustment Fund projects were not completed by the original deadline. The government dealt with them in a variety of ways. These included granting an additional construction season for project completion, transferring the projects to

existing programs, and cutting off federal funding and holding the recipients responsible for completing projects at their own cost.

1.62 We noted that a number of factors contributed to delays for Community Adjustment Fund projects, including weather problems, the need to obtain approvals, and, in the case of the Federal Economic Development Agency for Southern Ontario, the one-year time frame for project completion.

Stricter conditions were applied to extended projects

- 1.63 To increase assurances that federal stimulus funding would be spent by the new deadline of 31 October 2011, recipients requesting an extension had to obtain government approval for new project conditions. We looked for evidence that extended projects met the new conditions, including detailed spending forecasts and construction schedules that were signed by a professional engineer or architect.
- 1.64 Failure to meet the original 31 March 2011 deadline partly reflected the risk of relying solely on applicants' attestations of project readiness and their ability to complete an infrastructure project within two years. We had identified this risk in our first audit of the Economic Action Plan. The conditions for extension were important to assure the government that funding for projects would be spent by the new deadline and would thus contribute toward the Economic Action Plan objective of stimulating the economy in a timely manner. The deadline extension also allowed projects to be completed without losing federal funding.
- 1.65 We examined a representative sample of extended Infrastructure Stimulus Fund and Knowledge Infrastructure Program projects to determine whether they complied with the new conditions for extension. We found that all projects met the conditions. At the time of our audit, most were expected to be completed by 31 October 2011.
- 1.66 According to federal officials and recipients, factors such as weather, fires, floods, and availability of labour and materials had affected the ability to complete projects within the original time frame. We also noted that despite attestations of construction readiness, municipalities sometimes waited to complete planning and engineering work for infrastructure projects until they had secured project funding. We further observed that several projects granted an extension were large and complex. We visited four of these projects from our representative sample, where recipients opted for the extended time frame (Exhibit 1.5).

Exhibit 1.5 Some large and complex projects were extended

Expansion of Port of Belledune, New Brunswick

The Infrastructure Stimulus Fund provided \$26.4 million for a project to expand the Port of Belledune by adding multi-use cargo storage and constructing a barge terminal. This was a complex project involving many partners; according to the funding recipients, without the federal funding, it would not have been realized for many more years. Delays caused by the weather made it difficult to meet the construction schedule. The deadline was extended to 31 October 2011 to allow the recipients additional time to complete the project without compromising construction quality.



New heating and cooling system, University of Calgary, Alberta

The Knowledge Infrastructure Program provided \$29.8 million for a project to improve the university's outdated heating and cooling system. This new system was designed to increase energy efficiency and capacity, while decreasing emissions. Unexpected delays in the delivery of key equipment parts caused the project to miss the 31 March 2011 deadline for completion. An extension was granted and the university expected to complete the project by July 2011.



New medical building, Queen's University, Ontario

The Knowledge Infrastructure Program provided \$28.8 million to partly fund the new Queen's School of Medicine. The building houses simulation labs, innovative teaching spaces, teaching clinics, student study space, and advanced scientific laboratories. With the new facility, the University expects to increase enrolment by 25 percent, and will continue to train highly qualified medical professionals and researchers. Unexpected delays in obtaining custom materials put the project four to six weeks behind schedule. The only way to meet the original deadline of 31 March 2011 would have been by paying overtime costs. Instead, the university opted for a two-month extension.



Recreational facilities, Stoney Creek, Ontario

The Infrastructure Stimulus Fund provided \$4.3 million in funding for a project to renovate an existing arena and construct a new recreational facility. The project was not construction-ready. After funding was granted, it had to obtain municipal permits and approvals as well as undergo a complex design phase, a public consultation process, and environmental and archaeological studies. The work is expected to continue until summer of 2012. Infrastructure Stimulus Fund funding will be provided for the eligible federal portion of costs incurred up to 31 October 2011.



Program design did not allow for assessment of the key objective of job creation

1.67 A key objective of the Economic Action Plan was to stimulate the economy by creating jobs. In our first audit, we reported that the use of project-level information from Economic Action Plan programs could not provide a consistent measure of jobs created under the Plan overall. Instead, the government intended to rely on an analysis based on a macroeconomic model to estimate the number of jobs created or maintained. Consequently, central agencies notified departments and agencies delivering Economic Action Plan programs that the government would not be relying on project-level estimates of jobs created as a measure of the plan's overall success.

- 1.68 As part of our monitoring objective for this audit, we examined whether departments and agencies collected information on the progress of projects. Under federal policy, departments and agencies should have monitored overall progress, including whether recipients were collecting and reporting the information required for government officials to determine whether a project was being completed as intended.
- 1.69 Of the three programs we examined, the Community Adjustment Fund was designed to support projects intended to create and maintain employment. Collecting information on job creation was important because one of the key objectives of the fund was to support or create jobs in communities that had experienced significant job losses and lacked other employment opportunities for people who were out of work.
- 1.70 We found that contribution agreements for Community Adjustment Fund projects included specific performance indicators related to job creation. The performance indicators were designed to be used as a measurement of project progress. However, in the absence of guidance on how to consistently collect job information, performance information was collected in a variety of ways and, in one case, was not systematically collected after central agencies announced that job information would be used selectively only for illustrative purposes to accompany the macroeconomic analysis. The lack of reliable performance information on job creation will make it difficult for the government to assess the Community Adjustment Fund program's effectiveness in meeting one of its key objectives.
- 1.71 Recommendation. When federal initiatives to be delivered by multiple federal entities are developed, the sponsoring departments, in consultation with the Treasury Board of Canada Secretariat, should ensure that programs are designed to allow for reliable performance measurement and reporting on overall impact and effectiveness.

The Department's and regional development agencies' response. Agreed. When delivering new national programming, Industry Canada and regional development agencies will work with federal delivery partners and in consultation with the Treasury Board of Canada Secretariat to ensure reliable performance measurement and reporting on overall program impact and effectiveness.

The Secretariat's response. Agreed. As part of its regular business and as requested by sponsoring departments, the Secretariat will continue to provide advice and guidance on performance measurement and reporting in the design of programs delivered by multiple departments.

Departmental performance reports for the 2009–10 fiscal year did not provide an overall picture of Economic Action Plan program performance

- 1.72 Under the Economic Action Plan, departments and agencies were required to report on the implementation and effectiveness of their Economic Action Plan programs through their departmental performance reports. In May 2010, the Secretariat issued guidance about reporting on the performance of Economic Action Plan programs in departmental performance reports for the 2009–10 fiscal year. The reports were to provide information on actual progress and spending of Economic Action Plan programs. The first audit of the Economic Action Plan recommended that departments delivering programs under the Plan report to Parliament by devoting a separate section in their annual departmental performance reports to the spending and results of those programs.
- 1.73 This is important because departmental performance reports are intended to provide information to parliamentarians and Canadians about results achieved against planned performance expectations and public resources spent. The 2009–10 departmental performance reports were supposed to provide progress information on how the federal government spent \$47 billion of public funds for the Economic Action Plan.
- 1.74 We found that other sources of information on the three audited programs were available to parliamentarians. These included government reports on the Economic Action Plan, Parliamentary Budget Officer reports, department and agency websites, and testimony by department officials during parliamentary committee hearings. However, this information was prepared for different purposes, at different times, and for dissemination through different channels.
- 1.75 In the departmental performance reports submitted to Parliament in fall 2010, we examined whether departments and agencies followed the Secretariat's guidance on the way to present information about progress and spending under the three Economic Action Plan programs.
- 1.76 We found that Infrastructure Canada's 2009–10 Departmental Performance Report provided information on progress and spending under the Infrastructure Stimulus Fund, while Industry Canada's 2009–10 Departmental Performance Report provided information concerning the Knowledge Infrastructure Program. However, we found that, overall, the regional development agencies and Industry Canada's information in departmental performance reports on the Community Adjustment Fund was incomplete: the information lacked details on

the expected results and did not give a summary of performance to date. Consequently, it was difficult to assess program progress.

- 1.77 In its guidance for departmental performance reports, the Secretariat asked that departments identify their expected Economic Action Plan results, performance indicators, and targets as outlined in their reports on plans and priorities for the 2009–10 fiscal year. Several officials from the regional development agencies delivering the Community Adjustment Fund projects that we audited told us that they could not provide this information in their 2009–10 departmental performance reports, because their reports on plans and priorities had been written before the details of Economic Action Plan programs were known. Agency officials indicated that the information on program performance would be more comprehensive in departmental performance reports for the 2010–11 fiscal year.
- 1.78 Following the Secretariat's guidance, Infrastructure Canada, Industry Canada, and the regional development agencies reported performance information on their Economic Action Plan programs in various places throughout their departmental performance reports. According to Secretariat officials, this method of reporting was chosen to ensure consistency and alignment with the structure of the Estimates documents. In our view, the fragmented presentation made it difficult for parliamentarians and Canadians to obtain an overall picture of results achieved against planned performance expectations and public resources spent.
- **1.79 Recommendation.** In its future guidance for departmental performance reports, the Treasury Board of Canada Secretariat should encourage departments and agencies to consolidate Economic Action Plan reporting in a separate sub-section of their departmental performance reports.

The Secretariat's response. Agreed. The Secretariat released the 2010–11 guidance for the Departmental Performance Report to federal departments and agencies on 18 July 2011. The guidance provides a specific request to report Economic Action Plan information, where feasible, at the end of Section II of the report.

Central agencies intend to issue a report on the impact of the Economic Action Plan

1.80 In our first audit of the Economic Action Plan, we recommended that the Department of Finance Canada and the Privy Council Office prepare a summary report to Parliament at the conclusion of the Economic Action Plan, including a detailed account of the plan's impact on the economy.

- 1.81 In their response, the Privy Council Office and the Department of Finance Canada committed to supporting the government in its reporting on the delivery and economic impact of the Economic Action Plan, building on the five reports to Canadians that had been provided up to fall 2010. The Department of Finance was monitoring the impact of the Economic Action Plan and planned to prepare a final report on it.
- 1.82 In this audit, the Privy Council Office and the Department of Finance Canada informed us that, building on the reports to Canadians published to date, the government intends to submit a summary report on the delivery and economic impact of the Economic Action Plan to Parliament once sufficient information is available, probably by late 2011 or early 2012.
- 1.83 Department of Finance Canada officials also indicated that a summary of Economic Action Plan spending results for the 2010–11 fiscal year would be included in the Annual Financial Report and Public Accounts, to be released in fall 2011. In addition, the Department is planning to provide spending results related to the extension of selected Economic Action Plan programs in the Annual Financial Report and Public Accounts for the 2011–12 fiscal year, to be released in fall 2012.

Delivering time-sensitive programs

The experience of delivering Economic Action Plan programs has provided important lessons

- 1.84 To meet the Economic Action Plan's objective of stimulating the economy quickly, the federal government faced the necessity of designing and implementing programs within a limited time frame. In a March 2009 letter to the President of the Treasury Board, the Auditor General of Canada acknowledged the challenges presented by the Economic Action Plan. At the same time, she stressed the importance of balancing the government's wish to move quickly with the requirement to give due attention to the spending of a significant sum of public funds.
- 1.85 In our first audit of selected Economic Action Plan programs, we found that the government had adequately managed the selected programs: it put in place appropriate management practices and provided programs to eligible recipients in a timely manner. As recommended in our first audit, it is important that the federal government consider the lessons it has learned and the best practices it has developed during the design and implementation of the Economic Action Plan, and that it document these for consideration in future federal programming.

- 1.86 In both audits, we observed that departments and agencies took the initiative to develop new processes that could benefit regular federal programming. The following are some of our observations, together with the insights gained by departments and agencies from the delivery of time-sensitive programs.
- 1.87 Lessons learned from the first Economic Action Plan audit include the following:
 - Review documents for Cabinet committees and submissions for Treasury Board financial approval at the same time if there is a need to accelerate the design and approval of new programs.
 - To accelerate implementation, deliver new programs through existing program and delivery mechanisms.
- 1.88 Lessons learned from the second Economic Action Plan audit include the following:
 - · Project approvals require a detailed project schedule. These are intended to provide increased assurances that each project will meet required deadlines if a program has a compressed time frame.
 - For large and complex infrastructure projects, introduce additional assurances by engaging professionals (engineers, architects) during the approval phase of projects.
 - When relying on the provinces and territories to monitor contribution agreements, collect timely information to confirm that projects are being completed as intended and that committed federal funds allocated to projects are spent.
 - Ensure that Parliament obtains an overall picture of results achieved against planned performance expectations and public resources spent.

Conclusion

- 1.89 For the three Economic Action Plan programs we audited, we found that the federal government monitored progress and spending of projects, and reported performance information on their Economic Action Plan programs.
- 1.90 Infrastructure Canada, Industry Canada, and the regional development agencies collected project information that allowed them to take corrective action if projects were falling behind schedule. As well, the Infrastructure Stimulus Fund, Knowledge Infrastructure

Program, and Community Adjustment Fund largely achieved the Economic Action Plan objective to spend federal funding, in a timely manner, by 31 March 2011. However, the total federal spending for the three programs will be known only when the federal departments and agencies receive final project claims and close-out reports.

- 1.91 We found that the government's decision to extend the 31 March 2011 deadline for the Infrastructure Stimulus Fund and the Knowledge Infrastructure Program was based on a central agency analysis; this considered the information on project progress, the risk of stopping federal funding before the Economic Action Plan investments could be realized, and the strength of the economic recovery in Canada and globally.
- 1.92 One of the key objectives of the Community Adjustment Fund was to create or maintain jobs in communities hit hard by the economic downturn. It remains unclear how the government will assess the effectiveness of the Community Adjustment Fund program in achieving this objective.
- 1.93 Following guidance from the Treasury Board of Canada Secretariat, Infrastructure Canada, Industry Canada, and the regional development agencies reported performance information on their Economic Action Plan programs in various places throughout their departmental performance reports. According to Secretariat officials, this method of reporting was chosen to ensure consistency and alignment with the structure of the Estimates documents. In our view, the fragmented presentation made it difficult for parliamentarians and Canadians to obtain an overall picture of results achieved against planned performance expectations and public resources spent.

About the Audit

All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by The Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

Objective

The objective of our audit was to determine whether selected federal departments and agencies monitored and reported on progress and federal spending for selected Economic Action Plan programs.

Scope and approach

Our audit focused on the federal government's monitoring and reporting on progress and spending for selected programs of Canada's Economic Action Plan. We restricted our scope to three programs. The scope included two departments and five regional development agencies for detailed audit work: Intrastructure Canada and Industry Canada, the Atlantic Canada Opportunities Agency, the Economic Development Agency of Canada for the Regions of Quebec, Western Economic Diversification Canada, the Federal Economic Development Agency for Southern Ontario, and the Canadian Northern Economic Development Agency. The Federal Economic Development Initiative for Northern Ontario is an Industry Canada initiative that delivered the Community Adjustment Fund together with the five regional development agencies.

We also looked at the role of the central agencies—the Treasury Board of Canada Secretariat, Department of Finance Canada, and the Privy Council Office—in the decision to extend the project deadline.

Separate statistically representative samples were extracted from the populations of interest, namely

- the Infrastructure Stimulus Fund, terminating on 31 March 2011;
- the Infrastructure Stimulus Fund, extended to 31 October 2011;
- the Knowledge Infrastructure Program, terminating on 31 March 2011;
- the Knowledge Infrastructure Program, extended to 31 October 2011; and
- the Community Adjustment Fund, terminating on 31 March 2011.

A total of 236 projects were selected from the combined population of 5,778. Individual sample sizes were sufficient in each case to conclude on the respective populations with a confidence level of 90 percent and a confidence interval of > 10 percent. Eight of the 236 sampled projects were also used as illustrative cases.

In addition, 8 of the 42 newly approved Infrastructure Stimulus bund projects and both newly approved Knowledge Infrastructure Program projects were selected for our review of project eligibility.

Criteria

Criteria	Sources		
Federal departments and agencies monitor overall project progress, including whether projects are being completed as	Policy on Management, Resources and Results Structures, Treasury Board, 2010		
intended, for selected Economic Action Plan programs.	Policy on Transfer Payments, Treasury Board, 2008		
	Directive on Transfer Payments, Treasury Board, 2008		
Central agencies undertake an analysis to inform the decision to extend the project completion deadline for selected Economic	 Privy Council Office, 2010–11 Report on Plans and Priori "Operational Priority 1" 		
Action Plan programs.	Department of Finance Canada, 2010–11 Report on Plans and Priorities		
Newly approved projects, as of 20 December 2010, for the Infrastructure Stimulus Fund and the Knowledge Infrastructure Program meet eligibility criteria, including demonstrating that	Program terms and conditions for the Knowledge Infrastructure Program, the Infrastructure Stimulus Fund, and the Community Adjustment Fund		
they will meet the 31 March 2011 deadline.	Policy on Transfer Payments, Treasury Board, 2008		
	nitored federal spending for selected Economic Action Plan programs, llowing criteria: Sources		
AND CONTRACT OF THE PROPERTY O			
Federal departments and agencies monitor federal spending, including operating costs, for selected Economic Action Plan	Policy on Transfer Payments, Treasury Board, 2008 Directive on Transfer Payments, Treasury Board, 2008		
including operating costs, for selected Economic Action Plan			
	 Policy of Transfer Payments, Treasury Board, 2008 Directive on Transfer Payments, Treasury Board, 2008 Policy on Management, Resources and Results Structures, Treasury Board, 2010 		
including operating costs, for selected Economic Action Plan	Directive on Transfer Payments, Treasury Board, 2008 Policy on Management, Resources and Results Structures,		
including operating costs, for selected Economic Action Plan programs. To determine whether selected federal departments and agencies reported	 Directive on Transfer Payments, Treasury Board, 2008 Policy on Management, Resources and Results Structures, Treasury Board, 2010 Program terms and conditions for the Knowledge Infrastructure Program, the Infrastructure Stimulus Fund, and the 		
including operating costs, for selected Economic Action Plan programs. To determine whether selected federal departments and agencies reported	 Directive on Transfer Payments, Treasury Board, 2008 Policy on Management, Resources and Results Structures, Treasury Board, 2010 Program terms and conditions for the Knowledge Infrastructure Program, the Infrastructure Stimulus Fund, and the Community Adjustment Fund to Parliament, through their Departmental Performance Reports, on progress 		
including operating costs, for selected Economic Action Plan programs. To determine whether selected federal departments and agencies reported and actual spending for selected Economic Action	Directive on Transfer Payments, Treasury Board, 2008 Policy on Management, Resources and Results Structures, Treasury Board, 2010 Program terms and conditions for the Knowledge Infrastructure Program, the Infrastructure Stimulus Fund, and the Community Adjustment Fund to Parliament, through their Departmental Performance Reports, on progress on Plan programs, we used the following criteria:		

Management reviewed and accepted the suitability of the criteria used in the audit.

Period covered by the audit

Audit work for this chapter covers the period from February 2009, when Budget 2009 came into force, to 31 March 2011.

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Appendix List of recommendations

The following is a list of recommendations found in Chapter 1. The number in front of the recommendation indicates the paragraph where it appears in the chapter. The numbers in parentheses indicate the paragraphs where the topic is discussed.

Response Recommendation Monitoring progress and spending 1.71 When federal initiatives to be The Department's and regional development agencies' delivered by multiple federal entities are response. Agreed. When delivering new national programming, developed, the sponsoring departments, Industry Canada and regional development agencies will work in consultation with the Treasury Board with federal delivery partners and in consultation with the of Canada Secretariat, should ensure Treasury Board of Canada Secretariat to ensure reliable that programs are designed to allow for performance measurement and reporting on overall program reliable performance measurement and impact and effectiveness. reporting on overall impact and The Secretariat's response. Agreed. As part of its regular effectiveness. (1.67-1.70) business and as requested by sponsoring departments, the Secretariat will continue to provide advice and guidance on performance measurement and reporting in the design of programs delivered by multiple departments. 1.79 In its future guidance for The Secretariat's response. Agreed. The Secretariat released departmental performance reports, the the 2010-11 guidance for the Departmental Performance Treasury Board of Canada Secretariat Report to federal departments and agencies on 18 July 2011. should encourage departments and The guidance provides a specific request to report Economic agencies to consolidate Economic Action Plan information, where feasible, at the end of Section II Action Plan reporting in a separate subof the report. section of their departmental performance reports. (1.72-1.78)

Report of the Auditor General of Canada to the House of Commons—Fall 2011

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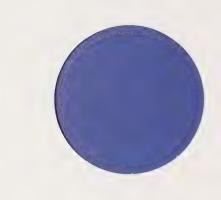
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The Fall 2011 Report of the Auditor General of Canada comprises Matters of Special Importance, Main Points—Chapters 1 to 5, Appendices, and five chapters. The main table of contents for the Report is found at the end of this publication.

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Chapter

2

Issuing Visas

Performance audit reports

This report presents the results of a performance audit conducted by the Office of the Auditor General of Canada under the authority of the Auditor General Act.

A performance audit is an independent, objective, and systematic assessment of how well government is managing its activities, responsibilities, and resources. Audit topics are selected based on their significance. While the Office may comment on policy implementation in a performance audit, it does not comment on the merits of a policy.

Performance audits are planned, performed, and reported in accordance with professional auditing standards and Office policies. They are conducted by qualified auditors who

- establish audit objectives and criteria for the assessment of performance;
- gather the evidence necessary to assess performance against the criteria;
- · report both positive and negative findings;
- · conclude against the established audit objectives; and
- make recommendations for improvement when there are significant differences between criteria and assessed performance.

Performance audits contribute to a public service that is ethical and effective and a government that is accountable to Parliament and Canadians.

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Issuing Visas

Main Points

What we examined

People from other countries—foreign nationals—who want to enter Canada as permanent residents must obtain a Canadian visa. Foreign nationals who want to enter Canada on a temporary basis must also apply for a visa, unless they are from a visa-exempt country. To obtain a visa, foreign nationals must meet all requirements for the category under which they are applying and must be deemed to be admissible. In 2010, 1.36 million visas (including 317,000 permanent resident visas) were processed at Canadian missions in foreign countries.

Admissibility of foreign nationals into Canada falls under the Immigration and Refugee Protection Act. The Act defines various situations where a foreign national would be inadmissible—for example, if the individual presents a risk to the health, safety, or security of Canadians. Administering the various provisions of the Act is a shared responsibility between Citizenship and Immigration Canada (CIC) and the Canada Border Services Agency (CBSA).

Before issuing a visa, CIC officials must determine that the applicant is admissible to Canada. They are supported in making this determination by the CBSA, which—with the help of the Canadian Security Intelligence Service (CSIS) and the Royal Canadian Mounted Police (RCMP)—coordinates and provides intelligence information related to the applicants.

We examined whether Citizenship and Immigration Canada and the Canada Border Services Agency have managed the risks associated with determining admissibility before issuing a visa, in line with the objective of the Act to protect the health, safety, and security of Canadians.

Audit work for this chapter was substantially completed on 29 April 2011.

Why it's important

Global events in the last decade have changed the nature of threats to Canadian society. Diseases prevalent in other countries that can be transmitted rapidly worldwide, incidents of terrorism, and organized crime around the world have shown the importance of identifying individuals who present a risk and preventing their entry into Canada.

Identifying visa applicants who are inadmissible to Canada is a highly complex process that relies heavily on the judgment and experience of CIC's visa officers in missions overseas and on the information made available to them. Visa officers are expected to make the best decisions they can with that information in the time they have available. It is critical that visa officers receive from their security and medical partners timely and reliable information on applicants.

What we found

- Citizenship and Immigration Canada and the Canada Border Services Agency have taken some measures to address long-standing weaknesses in the process of determining whether visa applicants are admissible to Canada. However, deficiencies still exist in the measures used to identify foreign nationals who may be inadmissible for health, safety, or security concerns. CIC and the CBSA lack the necessary tools and information to provide assurance that risks related to the admissibility determination process are properly managed.
- Some of the tools and risk indicators that visa officers use to identify inadmissible persons, and to know when to seek advice from security partners, are not kept up to date, nor are they always available.
 Furthermore, many CBSA analysts who provide security advice to visa officers have not received the necessary formal training to do so.
 Documentation to support the advice sent to visa officers offered little insight into how the analysts made their assessments, and in many cases not all the checks that should have been done were completed.
- CIC lacks guidance on the use of two key criteria used in medical screening—danger to public health and danger to public safety—although it has undertaken some work to explain what they mean. Medical screening to determine danger to public health has focused mainly on the same two diseases for the past 50 years—syphilis and tuberculosis. Although today 56 diseases require national surveillance in Canada, CIC has not reviewed whether foreign nationals should also be subject to mandatory testing for some of these diseases.

• CIC and the CBSA do not have systematic quality assurance practices or performance measures in place to know how well they are identifying individuals who are inadmissible because of health, safety, or security concerns. Most quality assurance practices that do exist focus on supporting decisions to refuse a visa. Because those decisions represent a very small percentage of applications each year, this means that the quality of decisions on the vast majority of applications is not reviewed.

The entities have responded. The entities agree with all of our recommendations. Their detailed responses follow the recommendations throughout the chapter.



Introduction

Legislative framework governing admissibility

- 2.1 The *Immigration and Refugee Protection Act*, which came into effect in 2002, governs immigration to Canada. One of its objectives is to protect the health and safety of Canadians and maintain the security of Canadian society. Citizenship and Immigration Canada (CIC) and the Canada Border Services Agency (CBSA) are jointly responsible for administering the Act and can deny entry to Canada for many reasons, including health, safety, or security concerns.
- 2.2 Citizenship and Immigration Canada enables foreign nationals to enter Canada as permanent or temporary residents by issuing visas. Under the Act, all applicants for permanent residence must obtain a visa before they can travel to Canada. A visa is also required for anyone applying for temporary residence, except citizens of countries where the Canadian government has granted a visa exemption. The temporary visa requirement applies to citizens of more than 140 countries. To obtain a visa, foreign nationals must meet all conditions for the category under which they are applying and must be admissible under the Act.
- 2.3 Officials of the Canada Border Services Agency are responsible for coordinating, with the Canadian Security Intelligence Service (CSIS) and the Royal Canadian Mounted Police (RCMP), information related to foreign nationals seeking entry into Canada and providing it to CIC officials to use when determining admissibility. Exhibit 2.1 shows the responsibilities for administering the key inadmissibility provisions of the Act related to health, safety, and security.
- 2.4 In 2010, CIC's visa officers abroad processed visa applications for 1.04 million people seeking temporary residence and for 317,000 people seeking permanent residence. These officers assess the information provided by applicants, collect additional information if needed, seek health and security advice from federal partners, and make a final decision based on their knowledge, judgment, and use of the tools available to them. Exhibit 2.2 shows the process for determining admissibility.
- 2.5 Visa officers work in a very complex operational environment. The type of applications they deal with and the risks to be assessed vary from one country to another. In addition, these officers can have a heavy workload. Meeting annual immigration targets and having service standards of a few days to issue temporary resident visas can make the application review process very demanding.

Visa officers —Either Canada-based officers or locally engaged visa officers. Canada-based officers are CIC employees sent abroad from Canada who have the designated authority to issue visas. Locally engaged visa officers are foreign nationals who are employed by a mission and have similar responsibilities to Canada-based officers, except that they don't have the authority to make security-related admissibility decisions.

Exhibit 2.1 Citizenship and Immigration Canada and the Canada Border Services Agency share responsibility for the inadmissibility provisions of the *Immigration and Refugee Protection Act*

Section of the Act	Responsibility for developing related policies	
Section 33: The facts that constitute inadmissibility under sections 34 to 37 include facts for which there are reasonable grounds to believe that they have occurred, are occurring, or may occur.		
Section 34 (Security): Applicants have engaged in spying, subversion, terrorism, or acts of violence, or they belong to organizations that have engaged in, or will engage in, these activities.	CBSA	
Section 35 (Human or international rights violations): Applicants have committed war crimes or crimes against humanity. They are or were senior members or officials of a government that has committed acts of terrorism, major human rights violations, genocide, war crimes, or crimes against humanity.	CBSA	
Section 36 (1) (Serious criminality): Applicants have been convicted of, or have committed, a crime punishable in Canada by a maximum term of imprisonment of at least 10 years. Section 36 (2) (Criminality): Applicants have been convicted of an offence punishable in Canada or have committed an act that is an offence in Canada.	CIC	
Section 37 (Organized criminality): Applicants belong to an organization that is believed to take part in organized criminal activity or to engage in transnational crimes such as people smuggling, trafficking in people, or money laundering.	CBSA	
Section 38 (Health): Applicants' health conditions are likely to be a danger to public health or public safety or may cause excessive demands on Canada's health or social services.	CIC	

Note: Other provisions related to inadmissibility, such as misrepresentation and financial reasons, were not addressed in the audit.

Source: Adapted from the Immigration and Refugee Protection Act

- 2.6 Visa officers must also ensure that negative decisions they make are well documented, since their work can be subject to appeals before the Immigration and Refugee Board or judicial reviews by the Federal Court.
- 2.7 During the audit, immigration services abroad were provided through 86 Canadian missions where about 270 Canada-based officers, 12 medical officers, and 1,305 locally engaged staff—including about 160 locally engaged visa officers—worked.

Mission—An office of the Government of Canada outside Canada. This includes an embassy or high commission, consulate general, and consulate.

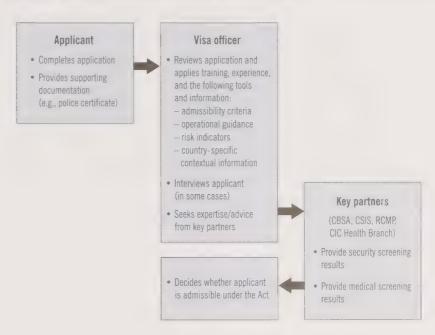


Exhibit 2.2 Process for determining admissibility when issuing visas

Our previous audit and subsequent events

- 2.8 In our April 2000 Report chapter, The Economic Component of the Canadian Immigration Program, we found that visa officers had little information and support to determine whether applicants were likely to engage in criminal activities or endanger the safety of Canadians. In addition, we identified a need for training to improve visa officers' decision-making skills. The audit also found weaknesses in the management of the medical admissibility process. We noted the need to define danger to public health and public safety and excessive demand on health care or social services to ensure that the Department was able to comply with the medical inadmissibility provisions of the Act—a need that we had also noted in our 1990 audit.
- 2.9 Since our 2000 audit, there have been major changes in the delivery of the immigration program. In 2002, the *Immigration and Refugee Protection Act* replaced the *Immigration Act* of 1976 and modified the criteria for admissibility.
- 2.10 The Canada Border Services Agency was created in December 2003, and responsibilities for intelligence, interdiction, and enforcement were transferred to it from CIC. In October 2004, the CBSA also became responsible for the immigration program at the ports of entry.

- 2.11 In July 2008, CIC and the Public Health Agency of Canada (PHAC) signed a memorandum of understanding outlining the Department's responsibilities for health in immigration. The PHAC is responsible for providing technical support to the Department on national public health issues, while CIC is responsible for policy development related to its mandate in immigration.
- 2.12 Global events in the last decade have also significantly changed the threats to Canadian society. For example, health risks originating in other countries can be transmitted rapidly worldwide by travellers, and terrorist attacks around the world have heightened Canadians' awareness of security risks.

Focus of the audit

- 2.13 The primary objective of our audit was to determine whether Citizenship and Immigration Canada and the Canada Border Services Agency have managed the risks associated with determining admissibility under the Act's provisions related to health, safety, and security before issuing visas to foreign nationals. We did not look at other inadmissibility provisions of the Act, such as misrepresentations or financial reasons, nor did we examine exemptions or means to overcome inadmissibility. Furthermore, we did not examine other strategies used by CIC or the CBSA to deny access to foreign nationals who could be a threat to Canada: for example, the interception overseas of improperly documented travellers en route to Canada, screening at ports of entry, or enforcement activities.
- 2.14 Our audit work was conducted primarily at the national headquarters of both organizations as well as at CSIS and the RCMP. We also visited six missions overseas that issued visas. Finally, we conducted a survey of all CIC visa officers involved in admissibility decisions overseas.
- 2.15 The audit focused on the process followed by visa officers overseas to make an admissibility decision before issuing a visa. The period covered by this audit was mainly from January 2010 to April 2011, and the audit work was substantially completed on 29 April 2011.
- 2.16 More details about the audit objective, scope, approach, and criteria can be found in About the Audit at the end of this chapter.

Observations and Recommendations

Determining admissibility

2.17 Citizenship and Immigration Canada (CIC) visa officers are responsible for determining the admissibility of applicants to Canada before issuing visas. This process requires an understanding of the Immigration and Refugee Protection Act, which governs immigration to Canada. The admissibility determination process relies heavily on information provided by the applicant, who is legally obligated to respond honestly to questions on the application form. Some applicants, however, may provide false information or fraudulent documentation. The admissibility determination process, therefore, relies on visa officers' judgment, training, and experience to analyze and validate information they receive from applicants. Visa officers also take into consideration the information provided by key partners. They are expected to make the best decisions they can with the information they have available. According to CIC data, of the applications processed in 2010 for 317,000 people seeking permanent residence, close to 69,000 applicants were refused, including 817 for health, safety, or security concerns. In 2010, CIC also processed applications for close to 1.04 million people seeking temporary residence and rejected about 189,000 applicants. At the time of our audit, information indicating which of these cases were rejected for health, safety, or security concerns was not available.

2.18 Given the challenging context in which visa officers operate, they need to be supported with adequate training and tools to do their job effectively, particularly in situations where the visa officer has not yet had job experience to draw upon.

Visa officers' initial training is good and a support network exists

- 2.19 At the time of our audit, about half of the Canada-based officers posted abroad and responsible for determining admissibility had less than five years of experience in issuing visas. We examined whether CIC developed and implemented training to ensure that its officers have the competencies to do their jobs.
- **2.20** We found that the initial mandatory training on the Act offered to officers at the beginning of their careers is well structured and rigorous. In addition, refresher training is mandatory for officers who are returning to overseas positions after being in Canada in positions that did not involve processing visa applications.

- 2.21 Once posted at missions overseas, visa officers are expected to maintain their knowledge and keep up to date through self-training, consultation with peers, and experience gained while processing files. They may also receive formal and informal training overseas, although we found that this training is offered on an ad hoc basis and varies across missions. The annual completion of appraisals and learning plans can help identify training needs. However, there is no assurance that all visa officers receive the additional training they need to maintain and build on their knowledge. In their responses to a survey we conducted as part of our audit, visa officers indicated that the top sources of additional training in admissibility decision making were self-training (87 percent) and coaching by supervisors or colleagues at the mission (65 percent).
- 2.22 Visa officers also have access to a support network of colleagues and supervisors within the mission and can consult officials in Ottawa if necessary. In our survey, visa officers stated that they use the network often.

Visa officers need better tools to help identify potentially inadmissible applicants

- 2.23 We examined whether the tools visa officers need were developed and updated and whether the officers were informed of any updates and changes. We looked at
 - · operational guidance,
 - · screening manuals and risk indicators, and
 - · country-specific risk profiles.
- 2.24 Operational guidance, risk indicators, and country-specific risk profiles are the primary tools to inform visa officers of what risks to look for; therefore, these tools need to be kept current so that they are useful for identifying people who may be inadmissible. See our overall recommendation at paragraph 2,36.
- Operational guidance. We noted that operational guides and bulletins on procedures for applying the Act were available electronically to visa officers who, for the most part, found them useful and sufficient. However, the limited search capability within the hundreds of various manuals and bulletins hampered officers' ability to find the right information quickly or to ensure that they were complying with procedures, especially if officers were inexperienced. We also found that guidance was not always developed in a timely manner to reflect the impact that some court decisions have had on the processing of applications.

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Security concerns Risks 1 (8), to have the first and the first and the first are unit, issues as outlined in section 34 of the Act); human or international rights violations (section 35); and organized crime (section 37)

- 2.26 Screening manuals and risk indicators. Canada-based officers are provided with three different screening manuals that define the risk indicators to help them identify applicants who may be inadmissible for security concerns and to determine when to refer a file to security partners (the Canada Border Services Agency, the Canadian Security Intelligence Service, and the Royal Canadian Mounted Police) for advice. In their responses to our survey, 97 percent of Canada-based officers indicated that they rely on these manuals to assess risks.
- 2.27 The Canada Border Services Agency (CBSA) is responsible for updating risk indicators, but we found that two of the screening manuals had not been updated for several years; one of these was last updated in 1999. The third manual, which focuses on national security, had been updated more frequently and was going through another review at the time of our audit. However, despite the CBSA's responsibility under the Act for the inadmissibility provisions related to security concerns, the Agency was not directly involved in the review, which could lead to inconsistency between the three manuals.
- 2.28 We noted that very few applicants, referred by visa officers using the current risk indicators, were found to be likely inadmissible by security partners. In many cases, there may be no information or concerns related to applicants. Of the cases security partners worked on in 2010, only about 1 percent of applicants for temporary residence and 0.1 percent of applicants for permanent residence were found to be likely inadmissible (Exhibit 2.3). We noted that there has been no analysis to determine whether the current risk indicators to help identify potentially inadmissible applicants are appropriate or properly applied.

Exhibit 2.3 Only a small number of applicants who were referred to security partners were identified as likely inadmissible in 2010

Applicants*	Cases finalized by security partners	Applicants identified as likely inadmissible
Temporary residence	 socurity partitions	 -
946.000	74,000	622
Permanent residence		
257,000	42,000	46

^{*}Applicants subject to criminal and security checks include those 18 and over, or someone younger if concerns exist.

- 2.29 Country-specific risk profiles. We also found that, upon visa officers' arrival at a new mission, information on country-specific risks is not systematically provided to them. For example, during our site visits, we noted that some missions provided newly posted visa officers with important contextual information specific to the country. At other missions, officers commented that a lack of country-specific information was affecting their ability to make admissibility decisions.
- **2.30** The CBSA produces country assessment reports that provide another source of information to visa officers to help them identify risks. We found that these reports are not systematically produced and distributed to visa officers at missions abroad. They are produced based on emerging events or on an ad hoc basis to address a specific request by CIC and CBSA officials.
- **2.31** Measures for validating information from applicants. The reliability of information provided by applicants can be validated through measures such as
 - interviewing the applicant,
 - verifying documents with the issuing authorities,
 - seeking further documentation and clarification from applicants, or
 - conducting site visits.
- **2.32** These measures, however, require time and resources. For example, visa officers at missions we visited told us that face-to-face interviews were rarely conducted. Since CIC does not systematically track when interviews are conducted, data on interview frequency was not available. At the end of our audit, CIC was implementing a case management system that could allow it to collect interview data.
- 2.33 In response to our survey, 65 percent of visa officers indicated that the inability to validate applicant information was a challenge in determining admissibility. About half of the Canada-based officers indicated that they often did not have sufficient information from applicants to assess whether an applicant was inadmissible due to security concerns.
- 2.34 Similarly, assessing inadmissibility due to criminality concerns can be challenging. For example, applicants who intend to stay in Canada for a minimum of six months must submit a police certificate from an official issuing authority of each country where they have resided for longer than six months in the last ten years. We were told by visa officers at missions we visited that the authenticity of police

certificates was often difficult to validate, depending on the country of origin. Unless visa officers can confirm the information with reliable issuing authorities, few other mechanisms exist to verify that the applicant has not been convicted of any crimes.

- 2.35 At the end of our audit, CIC had developed and approved a Program Integrity Framework that highlights the need to conduct antifraud activities, such as verification of applicant information. CIC plans to phase in this framework over the next five years.
- **2.36** Recommendation. The Canada Border Services Agency and Citizenship and Immigration Canada should ensure that operational manuals, risk indicators, and relevant country-specific information are complete, up to date, and made available to visa officers in a timely manner to help them identify foreign nationals who may be inadmissible.

The entities' response. Agreed. A review of current risk indicators has begun in consultation with security partners. Also in consultation with security partners, a strategy will be developed to ensure that necessary country-specific information is available in a timely manner to support admissibility decision making. In addition, a review and update of policy manuals will be undertaken to ensure that accurate operational guidance is in place for all staff and management involved in the admissibility screening process. These measures will be completed by June 2012.

Quality assurance for issuing visas needs to be improved

- 2.37 Given the complexity of the process for issuing visas, we examined whether progress has been made in implementing a quality assurance framework to address recommendations we made in previous audits. Structured quality assurance practices can provide assurance on the overall quality of work performed and on how well risks are managed. For example, they can show whether risk indicators are applied as intended, screening is identifying inadmissible persons, and improvements are made as needed.
- 2.38 We found that CIC had not yet implemented the quality assurance framework it had developed in response to our 2000 audit. We noted that some missions undertake their own quality assurance activities to review decision making, depending on local priorities and the availability of resources. However, such activities are still not mandatory and are not performed systematically across missions.

2.39 The Department's 2011 Program Integrity Framework calls for the monitoring of the quality of decision making through random, systematic, and targeted quality assurance activities. We encourage CIC to implement this new framework in accordance with its approved plan and its commitment made in response to a recommendation in our November 2009 Report chapter, Selecting Foreign Workers Under the Immigration Program, to apply quality assurance in a consistent and risk-based fashion within two years.

Security screening

Security screening—Procedures used to identify foreign nationals who may be inadmissible because they are, have been, or are likely to be involved in activities related to espionage, terrorism, and subversion; human or international rights violations; or organized

- 2.40 Applicants aged 18 years and over are subject to criminal and security checks. (A visa officer can also request checks on someone younger if concerns exist.) First, visa officers examine the information and documentation submitted by the applicant. If they determine that an applicant requires a more detailed investigation, the applicant's file is referred to partners for security screening.
- 2.41 The Canada Border Services Agency (CBSA) is responsible for supporting the security screening of persons who may be inadmissible. The Agency is the central liaison for the security screening process in partnership with the Canadian Security Intelligence Service (CSIS) and the Royal Canadian Mounted Police (RCMP). The results of the security screening are key to visa officers when making a final determination of an applicant's admissibility.

The Canada Border Services Agency has not identified all information that may be available from its security partners

- 2.42 We examined whether Citizenship and Immigration Canada (CIC) and the CBSA have identified what information is available and useful, from the RCMP and CSIS, and whether they obtain it in a timely manner. Memoranda of understanding between CIC and its security partners state that relevant information held by partners will be provided on a timely basis.
- 2.43 We found that neither CIC nor the CBSA has conducted formal assessments to ensure that they have a thorough understanding of the nature and type of information that security partners could provide and that all key information needed to support security advice and recommendations is made available.
- 2.44 CSIS is the primary partner for security screening; it is involved in all screening requests related to national security. The RCMP has very limited involvement in the screening process. While the CBSA has access to some criminal databases, it does not systematically consult the RCMP to obtain intelligence on organized crime concerns.

- 2.45 We also found that since its creation, the CBSA has not signed memoranda of understanding or agreements on service levels with either of its security partners. Agreements related to obtaining information required for security screening date back to 2002 between CIC and CSIS and between CIC and the RCMP, before CBSA was created and given responsibility for security screening. During our audit, three of the organizations—the CBSA, CSIS, and CIC—initiated a review of their sharing of information for the purposes of screening foreign nationals.
- **2.46** The results of security screening depend on the information available to security partners and, in almost all cases, they have little or no evidence to suggest that foreign nationals seeking entry to Canada are inadmissible. However, where there is information, it is important that it be made available to visa officers in a usable and timely manner.
- **2.47** Recommendation. The Canada Border Services Agency should ensure that all information that can be obtained from security partners and is relevant to security screening is used to provide advice to Citizenship and Immigration Canada.

The Agency's response. Agreed. A comprehensive approach will be developed to ensure that all relevant information is available and shared with Citizenship and Immigration Canada (CIC). An assessment of information needs will take place in consultation with security partners, identifying any gaps and resulting in an information management strategy to ensure that necessary information can be accessed to support admissibility decision making. In addition, existing information-sharing arrangements between CIC, the Canada Border Services Agency, the RCMP, and the Canadian Security Intelligence Service will be reviewed to ensure that they are complete and serve the needs of the security screening program. These measures will be completed by March 2013.

The Canada Border Services Agency systems and practices need improvement to ensure that sound advice is provided to visa officers

2.48 The memorandum of understanding between CIC and the CBSA highlights the need to provide, in a timely fashion, necessary information to staff to perform their duties. We examined whether the CBSA has systems and practices in place to provide information and advice that support the decision-making needs of visa officers. We reviewed a representative sample of CBSA files finalized in 2010—109 temporary residence files and 50 permanent residence files. See our overall recommendation at paragraph 2.63.

- 2.49 Quality assurance and effectiveness. We found that the CBSA does not have a systematic quality assurance process to verify the quality and consistency of the reviews conducted by its analysts. The Agency's officials indicated that senior analysts review all negative briefs (inadmissibility recommendations) before sending them to the missions and that complex cases are often discussed with senior analysts or with management. However, negative recommendations represent less than one percent of the temporary residence workload and eight percent of the CBSA's permanent residence files. In our view, since the risk is that someone will be admitted to Canada who should not be, it is important to do quality assurance on all files and not just on the few where analysts make negative recommendations.
- 2.50 We also noted that the CBSA has not reviewed the effectiveness of its security screening process. It has not requested feedback from CIC on the usefulness of the information provided to visa officers, and there is no process to find out how they use the information. In our survey, about 45 percent of the Canada-based officers indicated that one of the challenges in determining the inadmissibility of an applicant is the lack of relevant information from security partners.
- 2.51 Timeliness of security screening. We also examined whether the results of the CBSA's security screening provided to Canada-based officers are timely. We found that, for the most part, the Agency responded in a timely manner for temporary residence cases.
- 2.52 The temporary residence screening manual indicates that the CBSA will reply to a visa officer's referral within 10 working days. Our file review showed that the CBSA responded to the missions within 10 working days in 80 percent of the cases. However, we found that in at least 25 percent of those cases, it had not waited for CSIS input before providing the security screening results. Therefore, the results provided to Canada-based officers did not include the CSIS review. This occurred because the CBSA's data system automatically sends a response to the missions after 10 days, unless an analyst has put a hold on the file. We were told, however, that if a concern is identified by CSIS after 10 days, the CBSA would notify the mission to stop the visa issuance. Nevertheless, the current practice allows for the exclusion of potentially important information due to the possibility that CSIS is unable to provide a response within 10 working days.
- For permanent residence cases, we noted that there was a formal agreement on service standards in the 2006 memorandum of understanding between CIC and the CBSA, which stated that advice will be provided to visa officers within 9 to 18 months. Through our

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file review, we found that the CBSA had completed its analysis in less than 9 months in 67 percent of the cases and exceeded 18 months in 19 percent of the cases.

- 2.54 We also reviewed a sample of 10 percent of the 72 permanent residence cases analyzed by the CBSA after CSIS had completed its review for national security concerns. In the cases we examined, we found that CSIS took an average of 34 months to provide its results to the CBSA when there was information requiring further investigation. We noted that the CBSA concurred with the advice provided by CSIS but, on average, it took an additional 9 months to send the advice to the visa officer without adding specific details about the individual.
- 2.55 In responding to our survey, 46 percent of the Canada-based officers indicated they were concerned with the length of time it can take to obtain information or advice from security partners. The CBSA has recognized that timeliness is a concern and, at the end of our audit, had initiated measures to improve the timeliness of its screening.
- **2.56** IT systems used in security screening. The CBSA relies on its Secure Tracking System, an automated system that processes and manages temporary residence cases. However, the system does not search through all information available from the Agency, whether in its intelligence products or in other databases.
- 2.57 Analysts can consult various other databanks. However, the Agency identified some concerns about these databanks in a 2011 report on the security screening unit. The report identified the following IT system risks:
 - The systems were not interoperable with those of security partners, which created barriers to obtaining necessary information in a timely manner.
 - Staff lacked complete access to all relevant CBSA systems, which created information gaps resulting in recommendations made by staff based on incomplete information.
 - The systems were old and needed to be replaced; the necessary upgrades and changes to modernize the systems were not a priority.

The report also indicated that actions were under way to mitigate the risks. We did not examine the implementation of these actions.

2.58 Training and support for Agency analysts. We examined the training provided to CBSA analysts to ensure that they have the necessary knowledge and skills to perform their duties. We found that

there was no formal training curriculum developed specifically for analysts based on required competencies, and that the Agency had already identified gaps in the training that was provided. For example, at the time of our audit, 39 percent of analysts had not received training in the provisions and requirements of the Immigration and Refugee Protection Act, and 74 percent were missing training in research techniques.

- 2.59 Analysts told us that in the absence of a formal training program, they rely mostly on guidance material, coaching, and on-the-job training to acquire the knowledge they need to fulfill their responsibilities. We noted that more than 40 percent of staff had two years of experience or less and that there was little stability at the senior levels to provide coaching and on-the-job training. The lack of training combined with staff turnover has contributed to an environment that cannot ensure that analysts are providing the best information or advice to visa officers.
- Our file review indicated that CBSA analysts did not consistently document the work they performed to provide advice on the admissibility of temporary residence applicants. We found such documentation in only 28 percent of the files reviewed. In those cases, analysts had listed the databases they consulted and indicated whether an Internet search was done but had not described the review performed or the information found. As a result, the Agency could not provide assurance that analysts had followed procedures or had conducted a full assessment.
- 2.61 In our review of permanent residence applicant files, we found that they were better documented and the reviews completed were more comprehensive than those for temporary residence. We were able to determine the extent of the review conducted by analysts in 70 percent of the files. Of these files, however, we found that all the mandatory checks were not completed in more than 80 percent of cases. CBSA analysts did not consult the required databases and open sources as per CBSA guidelines. Furthermore, they did not use the checklists that had been designed to guide them in their review to provide some assurance of completeness.
- At the end of the audit, CBSA senior management confirmed training as a priority and indicated that training needs were being identified for security screening analysts.

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2.63 Recommendation. The Canada Border Services Agency should

- implement a quality assurance process to ensure the consistency and quality of information and advice provided by analysts to Citizenship and Immigration Canada (CIC);
- ensure that analysts have adequate training, support, and tools to perform their duties;
- establish service standards for the timeliness of security screening based on the needs of CIC and its own capacity and that of its security partners; and
- measure the effectiveness of its security screening to ensure that it meets the needs of CIC in a timely manner.

The Agency's response. Agreed. The Canada Border Services Agency (CBSA) has restructured its security screening program to provide more focus on quality assurance and performance management. A review of training requirements for screening officers is under way and a high-level plan has been adopted to provide screening officers with a competency-based training program and supporting tools, to be implemented incrementally. In consultation with Citizenship and Immigration Canada and security partners, the CBSA will review service standards and make necessary program adjustments to ensure that the needs of all partners are met. These measures will be completed by December 2012.

Medical screening

- **2.64** Under the *Immigration and Refugee Protection Act*, foreign nationals are inadmissible for reasons of health if their health condition
 - is likely to be a danger to public health,
 - is likely to be a danger to public safety, or
 - might reasonably be expected to cause excessive demand on Canada's health or social services.

2.65 In order to assess an individual's health status, Citizenship and Immigration Canada (CIC) has 15 medical officers working in 10 regional medical offices worldwide. They oversee a network that includes laboratories, clinics, and more than 1,000 local physicians designated by CIC in 189 countries. Health infrastructure varies greatly from country to country, which adds to the challenge. These medical officers are responsible for ensuring that appropriate medical examinations are conducted and that visa officers are provided with any necessary information before making an admissibility determination.

Medical examination—A mandatory assessment for all applicants for permanent residence and their family members, whether or not they will accompany the applicant to Canada. A medical examination is required for some temporary residence applicants depending on their country of residence, length of stay, and planned activities in Canada— for example, working in an occupation in which the protection of public health is essential. Visa officers can also request a medical examination if they deem it necessary in other circumstances.

A better strategy is needed to protect the health and safety of Canadians

- 2.66 We examined the systems and practices in place to provide visa officers with timely and reliable information to assess if applicants are medically admissible. See our overall recommendation at paragraph 2.77.
- 2.67 Danger to public health and danger to public safety. In order to protect Canadians, there must first be a clear understanding of what constitutes a danger to public health and a danger to public safety to ensure that appropriate medical tests are conducted for foreign nationals applying to come to Canada. Although CIC has initiated work on what danger to public health and danger to public safety mean for immigration purposes, we found that the Department has not yet defined these two key provisions of the Act—a concern we also raised in our 1990 and 2000 audit reports.
- 2.68 At the time of our audit, the Department had defined only two diseases—syphilis and tuberculosis—as dangers to public health. These same two diseases have defined the screening practice for the last 50 years. We noted that mandatory HIV testing has been implemented since 2002, with the anticipated public health benefit of early detection, treatment, and prevention. Persons with HIV, however, will not be denied access to Canada for public health reasons. They would be found inadmissible only if their health condition might reasonably be expected to cause excessive demand on health or social services.
- 2.69 We also noted that the Department has not developed an overall strategy, based on risks, to screen for danger to public health. The Public Health Agency of Canada has identified 56 diseases that require national surveillance in Canada, but CIC has not conducted a review to determine whether foreign nationals should be subject to mandatory testing for some of these diseases in order to protect public health.
- 2.70 Some guidance exists on what medical conditions may constitute a danger for public safety. CIC has been focusing its screening on psychiatric conditions and drug/alcohol addiction. However, the Department's medical officers lack guidance to assess whether a person is likely inadmissible under this provision of the Act.
- 2.71 Excessive demand on health or social services. The Immigration and Refugee Protection Regulations define excessive demand on health or social services as a situation where
 - anticipated costs would likely exceed the average per capita cost of health or social services in Canada over a five- or ten-year period, or

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- the demand would add to existing waiting lists and increase the rate of mortality and morbidity of Canadians.
- 2.72 We examined the systems and practices in place to provide visa officers with timely and reliable information on whether an applicant might cause excessive demand on health or social services. CIC medical officers are required to assess the anticipated costs of providing health care and social services related to the health conditions of applicants. We found, however, that there are limits to their ability to accurately estimate these costs because information on provincial/territorial health care expenditures and wait times in Canada for the numerous health conditions that exist may not be available to them.
- 2.73 Furthermore, because of several court decisions, visa officers must also now consider non-medical factors, such as an applicant's ability and willingness to pay for services, or ability to obtain insurance. Visa officers explained to us that it is very difficult to assess the intent or capacity of an individual to pay. Concerns also exist about the unenforceable nature of an applicant's commitments once the person is residing in Canada.
- 2.74 Performance management. We found that, in 2010, CIC conducted more than 545,000 medical examinations resulting in some 1,200 applicants (0.22 percent) being found inadmissible for health reasons. Of those, less than 2 percent were considered a danger to public health or safety (the others were denied due to excessive demand on health or social services). CIC officials explained that persons who initially might not be admissible for public health reasons are able to enter Canada once they have been treated: for example, if they can demonstrate that their tuberculosis is inactive.
- 2.75 In our survey, visa officers indicated that they are provided with timely advice on medical admissibility. We found that CIC monitors the processing times only in those cases where applicants are admissible, and not in more complex cases, where applicants have conditions that could make them inadmissible.
- 2.76 At the time of the audit, CIC was in the process of implementing a new performance management framework to measure, monitor, and report on the efficiency and effectiveness of its health screening process.
- **2.77 Recommendation.** In order to meet the objectives of the *Immigration and Refugee Protection Act* to protect the health and safety of Canadians, Citizenship and Immigration Canada should

- develop a strategy based on risks to better identify applicants who
 present a danger to public health or a danger to public safety, and
- examine the methodology and process for assessing excessive demand on health and social services and take corrective measures as necessary.

The Department's response. Agreed. Citizenship and Immigration Canada (CIC) has initiated and continues to develop a risk assessment and management strategy to better address danger to public health and danger to public safety in the immigration context. Among the activities conducted are the completion of a discussion paper on defining danger to public health, and the completion of an HIV policy review. CIC will implement a strategy that will result in consistent admissibility criteria, standardized processes, and improved monitoring of its programs. These measures will be completed by September 2013.

CIC has started examining the excessive demand processes and will pursue its collaboration with the provinces and territories to review factors generating limitations and inconsistencies in the evaluation of excessive demands and will address the identified deficiencies. This measure will be completed by June 2013.

Better quality assurance is needed to manage and monitor medical risks

- 2.78 In order to ensure the reliability of the medical examination process and to mitigate the risk to program integrity, a robust quality assurance framework is needed to monitor the work of CIC-designated local physicians, laboratories, and X-ray clinics and provide information on results. We examined the quality assurance mechanisms for the medical reports prepared by those physicians and the procedures to monitor the effectiveness of medical screening.
- 2.79 We found that activities to assess the quality and reliability of the medical examinations performed by CIC-designated local physicians varied from one regional medical office to another, and a standard approach based on risks has not yet been developed.
- 2.80 We also noted that CIC had no standard approach for ensuring the quality or consistency of the work done by medical officers or by their staff when assessing medical admissibility. At the time of the audit, CIC was planning to implement an electronic medical system to improve the efficiency and effectiveness of medical assessments and to build in quality assurance mechanisms. The Department had also recently identified best practices in its regional medical offices to develop a standard quality assurance process.

2.81 Recommendation. Citizenship and Immigration Canada should implement a standard quality assurance process to protect the integrity of the medical examination system and to ensure consistency and quality in the assessment of medical admissibility.

The Department's response. Agreed. Citizenship and Immigration Canada (CIC) has already completed the development of a Quality Assurance Framework for its immigration medical examination and assessment programs. This framework will be integrated into the departmental Program Integrity Framework, providing the tool required to monitor and evaluate the quality of its immigration health program, worldwide, including the designated medical practitioners, other examiners, and CIC employees involved in the health assessment process. CIC is also in the process of implementing eMedical (an electronic medical system), enabling standardization and be completed by March 2013.

Governance, risk management, and performance measurement

2.82 The *Immigration and Refugee Protection Act* is highly complex, addressing all aspects of the immigration program. While Citizenship and Immigration Canada (CIC) and the Canada Border Services Agency (CBSA) are each responsible for developing policies for different sections of the Act, they share responsibility for the overall delivery of the immigration program. See our overall recommendation at paragraph 2.94.

Citizenship and Immigration Canada and the Canada Border Services Agency continue to clarify their relationship

- 2.83 Given their shared responsibility for achieving the Act's objectives, we examined whether the CBSA and CIC have defined their roles, responsibilities, and expectations regarding the admissibility provisions of the Act.
- 2.84 After immigration functions previously under CIC's responsibility were transferred to the CBSA, both organizations signed a memorandum of understanding (MOU) in 2006 to specify their respective roles and responsibilities. The Agency would provide guidance and support to the Department, and visa officers would be responsible for the final decisions on admissibility.
- 2.85 Since 2006, various reviews and senior-level joint committees have identified areas where the working relationship between the two organizations could be further clarified and strengthened. A 2010 joint internal audit on the implementation of the 2006 MOU

recommended improvements to governance and, in May 2011, a revised MOU and a governance annex were signed. Other annexes related to information management and shared services were still under negotiation at the end of our audit.

Joint risk management for admissibility determination needs to be implemented

- **2.86** In their policies, both CIC and the CBSA have recognized that risk management is an essential element of public sector operations and provides a systematic approach to the identification, analysis, assessment, treatment, and ongoing monitoring of risks.
- 2.87 In their response to a 2010 joint internal audit, CIC and CBSA agreed to develop an integrated approach to manage the risks related to the immigration program. We examined whether the two organizations have developed and implemented a joint risk management strategy for identifying risks and mitigation strategies related to applying the inadmissibility provisions of the Act.
- **2.88** We found that CIC and the CBSA have begun to develop a joint risk management strategy for the shared delivery of the immigration program. Although this strategy was not complete at the end of our audit, the Department and the Agency were working on a risk-based strategy for setting joint intelligence and enforcement priorities.
- 2.89 We are concerned, however, that joint risk management has not been implemented. CIC and CBSA had already identified in 2006 that quality assurance practices, the routine use of screening tools, and applicant interviews were needed as risk mitigation measures. This audit found deficiencies in each of these measures.

Performance measurement information is not available

- **2.90** As part of the process to develop a joint risk management strategy, CIC and the CBSA were also developing a joint performance measurement framework. Together, these initiatives were intended to provide officials with a means of understanding how well the two organizations were working together in the shared delivery of the immigration program.
- 2.91 We did note that progress had been made on developing a performance measurement strategy, but challenges remain in obtaining reliable performance information on security screening. For example, CBSA officials informed us that their information system was not designed to provide processing times or to identify the number of cases reviewed by an analyst versus those finalized by the automated system.

- **2.92** As well, the lack of quality assurance throughout the admissibility process has prevented the Department and the Agency from obtaining data to identify strengths and weaknesses in their systems, or obtaining information on how well their systems work to identify people who may be inadmissible for health, safety, and security concerns.
- 2.93 The two organizations have not measured the overall effectiveness of the inadmissibility provisions of the Act. However, during our audit, CIC and the CBSA were conducting a review of Canada's admissibility policy to assess whether it still meets Canadian needs, to identify any gaps, and to recommend amendments to relevant legislation, regulations, or administrative guidelines.
- **2.94** Recommendation. Citizenship and Immigration Canada and the Canada Border Services Agency should fully implement their joint risk management and performance measurement strategies and monitor the results.

The entities' response. Agreed. Citizenship and Immigration Canada (CIC) and the Canada Border Services Agency (CBSA) will implement and monitor their joint risk management and performance strategies for the shared delivery of the immigration and refugee program, including visa issuance. In this context, CIC and the CBSA will complete a review of Canada's admissibility policy, in collaboration with security partners, in order to assess whether it is continuing to meet the needs of Canada and Canadians; to identify any gaps; and to recommend amendments to relevant legislation, regulations, or administrative guidelines.

CIC and the CBSA will complete a joint priority-setting exercise based on key risks with respect to the intelligence program (including visa issuance) and resulting enforcement priorities. CIC and the CBSA will also complete work on key performance indicators with respect to visa issuance, which will be used to monitor the effectiveness of shared programs and to track the implementation of joint priorities.

These measures will be completed by December 2012.

Conclusion

2.95 Citizenship and Immigration Canada (CIC) and the Canada Border Services Agency (CBSA) have taken some measures to address long-standing weaknesses in the process of determining whether visa applicants are admissible to Canada. In our opinion, however, they have not fully managed the risks associated with determining inadmissibility under the *Immigration and Refugee Protection Act* for health, safety, and security concerns before issuing visas to foreign nationals.

- 2.96 CIC and the CBSA do not have systematic mechanisms for quality assurance or measuring performance that would provide a reasonable level of assurance that their processes are working and that practices are appropriate for today's challenges. Furthermore, the organizations have only recently begun to develop a joint risk management approach for their shared delivery of the immigration program.
- 2.97 Tools and guidance available to visa officers are not always kept up to date. The screening for danger to public health is still primarily based on the same diseases that have been the focus for the last 50 years. In addition, many risk indicators, key to identifying potentially inadmissible foreign nationals, have not been reviewed or updated for years.
- **2.98** Similar issues have been identified in our audits since 2000. There needs to be a sustained effort by CIC and the CBSA to address the gaps in the admissibility determination process so that the related risks are properly managed.

About the Audit

All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by The Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

Objective

The audit objective was to determine whether Citizenship and Immigration Canada (CIC) and the Canada Border Services Agency (CBSA) have managed the risks associated with determining admissibility under the *Immigration and Refugee Protection Act* for health, safety, and security concerns before issuing visas to foreign nationals.

Scope and approach

The audit examined how the Act's objective of "protecting the health and safety of Canadians and maintaining the security of Canadian society" was being jointly administered by the two primary entities involved in admissibility decisions—CIC and the CBSA. Our audit covered the process followed by visa officers to make the admissibility decision before issuing visas to foreign nationals seeking entry into Canada as either temporary or permanent residents. We did not look at other inadmissibility provisions of the Act, such as misrepresentations or financial reasons, nor did we examine exemptions or means to overcome inadmissibility.

The issuance of visas is one component of Canada's strategy to deny access to foreign nationals who may present risks to Canadians. Other components include, for example, the interception overseas of improperly documented travellers en route to Canada, screening at ports of entry, and enforcement activities, including investigation, detention, and removals. Our audit did not examine these activities.

At CIC, we interviewed officials at headquarters and at overseas missions involved in processing applications. We held focus groups with visa officers responsible for making admissibility decisions. We reviewed files and reports, and analyzed management information databases. We also met with medical officers who performed medical assessments on behalf of the Department. We conducted audit work at the following missions: Beijing, Buffalo, Damascus, London, Moscow, and Paris. We also met with officials from other organizations during our visits to missions overseas.

A survey was sent to 424 visa officers at missions abroad, and we received an overall response rate of 81.8 percent. Canada-based officers comprised 272 members of the survey population and provided a response rate of 79.0 percent, while locally engaged visa officers comprised 152 members and provided a response rate of 86.8 percent.

At the CBSA, we interviewed officials at headquarters and examined documents, files, and databases. Furthermore, we examined statistically representative samples of temporary (109 cases) and permanent (50 cases) residence cases referred to the Agency for security screening that were finalized in 2010. These

samples are sufficient to conclude on their respective populations with a confidence level of 90 percent and a margin of error of +10 percent.

Audit work was also conducted at RCMP and CSIS offices in Ottawa, mainly through interviews and review of key documents.

Criteria

Listed below are the criteria that were used to conduct this audit and their sources.

To determine whether Citizenship and Immigration Canada and the Canada Border Services Agency have clarified the expectations and their respective roles and responsibilities under the Immigration and Refugee Protection Act to jointly manage the risks associated with the determination of admissibility, we used the following criteria: Criteria Sources Citizenship and Immigration Canada (CIC) and the Canada Immigration and Refugee Protection Act Border Services Agency (CBSA) have clarified the expectations Immigration and Refugee Protection Regulations and their roles and responsibilities for the inadmissibility provisions of the Immigration and Refugee Protection Act. · Memorandum of understanding between the CBSA and CIC, 2006 Core Management Controls: A Guide for Internal Auditors, Office of the Comptroller General CIC and the CBSA have developed and implemented a joint Memorandum of understanding between integrated risk management strategy that identifies risks and the CBSA and CIC, 2006 mitigation strategies related to delivering the inadmissibility · Framework for the Management of Risk, provisions of the Immigration and Refugee Protection Act. Treasury Board, 2010 · Integrated Risk Management Framework, Treasury Board, 2001 Citizenship and Immigration Canada Integrated Risk Management Framework, 2002 · Corporate Risk Profile, Citizenship and Immigration Canada, 2010-2013 · Enterprise Risk Management Policy, Canada Border Services Agency, 2010 To determine whether Citizenship and Immigration Canada and the Canada Border Services Agency provide visa officers with the necessary training, tools, and support to analyze the information required to make a well-informed admissibility determination before issuing visas, we used the following criteria:

Criteria	Sources
CIC and the CBSA have identified, developed and provided training, tools, and support to visa officers for the determination of admissibility.	Memorandum of understanding between the CBSA and CIC, Information Sharing Annex, 2006
	Core Management Controls: Guide for Internal Auditors, Office of the Comptroller General
	Policy Framework for Information and Technology, Treasury Board, 2007

To determine whether Citizenship and Immigration Canada and the Canada Border Services Agency have systems and practices in place to make available to visa officers useful and timely information as well as advice to help them assess admissibility, we used the following criteria:

Odk. d	•	
Criteria	Sources	
CIC's Health Branch has systems and practices in place to provide visa officers with reliable and timely recommendations	OP 15 Medical Procedures, Citizenship and Immigration Canada	
on medical admissibility.	Designated Medical Practitioner Handbook, Citizenship and Immigration Canada	
CIC and the CBSA define and obtain, in a timely manner, useful information available on applicants from the RCMP and the Canadian Security Intelligence Service (CSIS).	 Memorandum of understanding between CIC and CSIS, 2002 Memorandum of understanding between CIC and the RCMP, 2002 Policy on information Management, Treasury Board, 2007 	
The CBSA has systems and practices in place to provide intelligence and advice that support the decision-making needs of visa officers.	 Memorandum of understanding between the CBSA and CIC, 2006 A Vision for the Intelligence Program at the CBSA, October 2006, CBSA 	

Management reviewed and accepted the suitability of the criteria used in the audit.

Period covered by the audit

With the exception of the audit work related to the memorandum of understanding between the CBSA and CIC, which came into effect in 2006, the period audited for this chapter is January 2010 to April 2011. Audit work for this chapter was substantially completed on 29 April 2011.

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Appendix List of recommendations

The following is a list of recommendations found in Chapter 2. The number in front of the recommendation indicates the paragraph where it appears in the chapter. The numbers in parentheses indicate the paragraphs where the topic is discussed.

Recommendation

Response

Determining admissibility

2.36 The Canada Border Services Agency and Citizenship and Immigration Canada should ensure that operational manuals, risk indicators, and relevant country-specific information are complete, up to date, and made available to visa officers in a timely manner to help them identify foreign nationals who may be inadmissible. (2.23–2.35)

The entities' response. Agreed. A review of current risk indicators has begun in consultation with security partners. Also in consultation with security partners, a strategy will be developed to ensure that necessary country-specific information is available in a timely manner to support admissibility decision making. In addition, a review and update of policy manuals will be undertaken to ensure that accurate operational guidance is in place for all staff and management involved in the admissibility screening process. These measures will be completed by June 2012.

Security screening

2.47 The Canada Border Services Agency should ensure that all information that can be obtained from security partners and is relevant to security screening is used to provide advice to Citizenship and Immigration Canada. (2.42–2.46)

The Agency's response. Agreed. A comprehensive approach will be developed to ensure that all relevant information is available and shared with Citizenship and Immigration Canada (CIC). An assessment of information needs will take place in consultation with security partners, identifying any gaps and resulting in an information management strategy to ensure that necessary information can be accessed to support admissibility decision making. In addition, existing information-sharing arrangements between CIC, the Canada Border Services Agency, the RCMP, and the Canadian Security Intelligence Service will be reviewed to ensure that they are complete and serve the needs of the security screening program. These measures will be completed by March 2013.

Recommendation

2.63 The Canada Border Services Agency should

- implement a quality assurance process to ensure the consistency and quality of information and advice provided by analysts to Citizenship and Immigration Canada (CIC);
- ensure that analysts have adequate training, support, and tools to perform their duties;
- establish service standards for the timeliness of security screening based on the needs of CIC and its own capacity and that of its security partners; and
- measure the effectiveness of its security screening to ensure that it meets the needs of CIC in a timely manner. (2.48–2.62)

Response

The Agency's response. Agreed. The Canada Border Services Agency has restructured its security screening program to provide more focus on quality assurance and performance management. A review of training requirements for screening officers is under way and a high-level plan has been adopted to provide screening officers with a competency-based training program and supporting tools, to be implemented incrementally. In consultation with Citizenship and Immigration Canada and security partners, the CBSA will review service standards and make necessary program adjustments to ensure that the needs of all partners are met. These measures will be completed by December 2012.

Medical screening

- 2.77 In order to meet the objectives of the Immigration and Refugee Protection Act to protect the health and safety of Canadians, Citizenship and Immigration Canada should
- develop a strategy based on risks to better identify applicants who present a danger to public health or a danger to public safety, and
- examine the methodology and process for assessing excessive demand on health and social services and take corrective measures as necessary. (2.64–2.76)

The Department's response. Agreed. Citizenship and Immigration Canada (CIC) has initiated and continues to develop a risk assessment and management strategy to better address danger to public health and danger to public safety in the immigration context. Among the activities conducted are the completion of a discussion paper on defining danger to public health, and the completion of an HIV policy review. CIC will implement a strategy that will result in consistent admissibility criteria, standardized processes, and improved monitoring of its programs. These measures will be completed by September 2013.

CIC has started examining the excessive demand processes and will pursue its collaboration with the provinces and territories to review factors generating limitations and inconsistencies in the evaluation of excessive demands and will address the identified deficiencies. This measure will be completed by June 2013.

Recommendation

2.81 Citizenship and Immigration Canada should implement a standard quality assurance process to protect the integrity of the medical examination system and to ensure consistency and quality in the assessment of medical admissibility. (2.78–2.80)

Response

The Department's response. Agreed. Citizenship and Immigration Canada (CIC) has already completed the development of a Quality Assurance Framework for its immigration medical examination and assessment programs. This framework will be integrated into the departmental Program Integrity Framework, providing the tool required to monitor and evaluate the quality of its immigration health program, worldwide, including the designated medical practitioners, other examiners, and CIC employees involved in the health assessment process. CIC is also in the process of implementing eMedical (an electronic medical system), enabling standardization and centralization of the medical examination process. These measures will be completed by March 2013.

Governance, risk management, and performance measurement

2.94 Citizenship and Immigration Canada and the Canada Border Services Agency should fully implement their joint risk management and performance measurement strategies and monitor the results. (2.82–2.93)

The entities' response. Agreed. Citizenship and Immigration Canada (CIC) and the Canada Border Services Agency (CBSA) will implement and monitor their joint risk management and performance strategies for the shared delivery of the immigration and refugee program, including visa issuance. In this context, CIC and the CBSA will complete a review of Canada's admissibility policy, in collaboration with security partners, in order to assess whether it is continuing to meet the needs of Canada and Canadians; to identify any gaps; and to recommend amendments to relevant legislation, regulations, or administrative guidelines.

CIC and the CBSA will complete a joint priority-setting exercise based on key risks with respect to the intelligence program (including visa issuance) and resulting enforcement priorities. CIC and the CBSA will also complete work on key performance indicators with respect to visa issuance, which will be used to monitor the effectiveness of shared programs and to track the implementation of joint priorities.

These measures will be completed by December 2012.

Report of the Auditor General of Canada to the House of Commons—Fall 2011

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2011



Report of the
Auditor General
of Canada
to the House of Commons

FALL

Chapter 3
Payments to Producers—
Agriculture and Agri-Food Canada



Office of the Auditor General of Canada



2011



Report of the Auditor General of Canada

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Chapter 3
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Agriculture and Agri-Food Canada





The Fall 2011 Report of the Auditor General of Canada comprises Matters of Special Importance, Main Points—Chapters 1 to 5, Appendices, and five chapters. The main table of contents for the Report is found at the end of this publication.

The Report is available on our website at www.oag-bvg.gc.ca.

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Chapter

3

Payments to Producers— Agriculture and Agri-Food Canada

Performance audit reports

This report presents the results of a performance audit conducted by the Office of the Auditor General of Canada under the authority of the Auditor General Act.

A performance audit is an independent, objective, and systematic assessment of how well government is managing its activities, responsibilities, and resources. Audit topics are selected based on their significance. While the Office may comment on policy implementation in a performance audit, it does not comment on the merits of a policy.

Performance audits are planned, performed, and reported in accordance with professional auditing standards and Office policies. They are conducted by qualified auditors who

- establish audit objectives and criteria for the assessment of performance;
- gather the evidence necessary to assess performance against the criteria;
- report both positive and negative findings;
- · conclude against the established audit objectives; and
- make recommendations for improvement when there are significant differences between criteria and assessed performance.

Performance audits contribute to a public service that is ethical and effective and a government that is accountable to Parliament and Canadians.

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Payments to Producers— Agriculture and Agri-Food Canada

Main Points

What we examined

Agriculture and Agri-Food Canada (AAFC) has a mandate to provide information, research and technology, and policies and programs to achieve an environmentally sustainable, innovative, and competitive agriculture sector. The Department's work includes supporting productivity and trade, stabilizing farm incomes, and conducting research. The federal government and the provinces and territories share responsibility for stabilizing farm incomes. Since 2008, they have done so through a joint federal/provincial/territorial agreement called the Growing Forward Framework Agreement.

The Department's programs have played an important role in supporting producers' incomes when market income has dropped. Our audit looked at two programs under Growing Forward that, like the Canadian Agricultural Income Stabilization (CAIS) program they replaced, are aimed at protecting agricultural producers from drops in income. AgriInvest is built around savings accounts, with producers' deposits matched by government contributions; AgriStability is a far more complex program designed to protect against larger drops in income. Costs of the two programs total \$1 billion annually, funded 60 percent by the federal government and 40 percent by provinces. About 88 percent of payments under the AgriStability program are now delivered by the provinces.

We also looked at the \$284 million Tobacco Transition Program, aimed at replacing the quota system, helping tobacco producers move out of the tobacco industry, and improving the viability of those who remain.

We looked at how the programs were developed, implemented, and administered. In particular, we looked at the quality of the risk assessment process and the process for continuous improvement. We also looked at the design and monitoring of funding and program delivery agreements between the Department and the provinces and territories or delivery organizations. We did not audit the provincial agencies or third-party organizations that participated in the delivery of programs.

Audit work for this chapter was substantially completed on 2 May 2011.

Why it's important

The Canadian agriculture and agri-food industry is vital to Canada's economic success and its food supply. It encompasses several industries, including primary agriculture, input suppliers, food and beverage processing and distribution, and wholesale and retail food industries. According to the Department, this industry accounted for 8.2 percent of total gross domestic product in 2009.

The agricultural sector faces several challenges, including increasing international competition, rapid technological improvements, increased importance of environmental and health concerns, increasing input costs, rapidly evolving consumer preferences, changes in foreign exchange, and more volatility due to weather changes and disease.

What we found

- To improve the design of its producer income support programs, Agriculture and Agri-Food Canada carried out industry consultation, a strategic review, producer surveys, and focus groups. Working with provinces and territories, the Department has made progress on some design issues, but long-standing concerns with AgriStability remain—clarity of program objectives, timely access to program funding, and program complexity that affects producers' ability to reasonably predict payment amounts.
- The Department has made progress in addressing program administration issues raised in our 2007 audit—for example, payment accuracy and management of underpayments to producers. However, it has not systematically followed up on causes of delays in payments to producers in order to accelerate payments. Despite improvement, the Department has not yet met its AgriStability processing time targets, and producers can wait up to two years after an income loss to receive a payment. In addition, the Department has not collected information on processing times for AgriInvest.
- Although federal/provincial/territorial accountabilities for performance reporting were not specified in the Growing Forward Framework Agreement, a performance measurement framework has since been agreed to by all governments. When fully implemented, overall national performance against service standards will be reported to Parliament and the public. With regard to assessing provincial capacity for AgriStability administration and transferring it to the provinces of British Columbia and Saskatchewan in 2010, the Department followed a sound process.
- The Department had to develop the Tobacco Transition Program
 within a short time frame and did not first conduct a thorough risk
 analysis. The agreement implementing the program did not provide
 clear terms and conditions to ensure that recipients would not enter

into business arrangements that would undermine the intent of the program. In addition, a number of times the Department changed its interpretation of what was and was not allowed under the Agreement, resulting in confusion for producers. As a result, the Department was successful in controlling some, but not all, business arrangements that it believed would undermine the intent of the program.

The Department has responded. The Department agrees with all of our recommendations. Its responses follow each recommendation throughout the chapter.



Introduction

Farm income support programs

- 3.1 Agriculture and Agri-Food Canada has a mandate to provide information, research and technology, and policies and programs to achieve an environmentally sustainable, innovative, and competitive agriculture sector. The Department's work includes supporting productivity and trade, stabilizing farm incomes, and conducting research. The Department has administered various farm income support programs since the late 1930s. The Department's programs have played an important role in supporting agricultural producers' incomes when market income has dropped.
- 3.2 In 2008, the Department entered into a joint federal/provincial/territorial agreement called the Growing Forward Framework Agreement. This five-year agreement expires on 31 March 2013, and a successor framework, called Growing Forward 2, is to be implemented on 1 April 2013. New framework agreements have to be negotiated and approved by federal/provincial/territorial governments.
- 3.3 The Growing Forward Framework Agreement includes two programs aimed at protecting agricultural producers from drops in income. AgriInvest is built around savings accounts, with producers' deposits matched by government contributions. For example, if a producer deposits \$1,000, the government will match this with \$1,000. There is a maximum that each producer can deposit. AgriStability is a far more complex program designed to protect against larger drops in income. AgriStability payments are based on specific farm information, such as the number and type of crops and livestock, and farm sales and expenses over a number of years.
- 3.4 Costs of the two programs total \$1 billion annually and are funded 60 percent by the federal government and 40 percent by provinces. For the 2009–10 fiscal year, the Department spent about \$15 million administering AgriInvest and \$40 million administering AgriStability. The provinces spent \$44 million to administer AgriStability in the same year.
- 3.5 AgriInvest and AgriStability have significant similarities to two predecessor programs, the Net Income Stabilization Account (NISA) and the Canadian Agricultural Income Stabilization (CAIS) program. Exhibit 3.1 provides a summary of farm income support programs from 1991 to present. In 2008, AgriStability, together with AgriInvest, replaced the coverage previously provided under the CAIS program.

- Agricultural producers—Those who produce
- livestock, poultry, related products (for example, eggs, dairy, and meat), and ranch fur products (for example, mink, fox);
- crop and plant products (for example, wheat, barley, oats, corn, fruit, nuts, vegetables, and tobacco); and
- nursery products (for example, trees, shrubs, annual and perennial plants).

Like the CAIS program, four provinces (Alberta, Ontario, 3.6 Quebec, and Prince Edward Island) delivered AgriStability from the start. Saskatchewan and British Columbia assumed program delivery in January 2010. The six provinces now deliver about 88 percent of AgriStability payment dollars, and the Department delivers the remaining 12 percent of payment dollars to the other provinces. Prior to 2010, the Department delivered about 34 percent of AgriStability payments to producers.

Exhibit 3.1 Summary of farm income support programs

Program years ¹	Annual program contribution	Number of participants	Criteria	Delivery organization
Net Income Stabilization Account (NISA) 1991–2002	\$347 million (1998–2002 average)	Over 144,466 (1998–2002 average)	Savings account matched by government funds—proof of loss required to access funds	Agriculture and Agri-Food Canada (AAFC)
Canadian Agricultural Income Stabilization (CAIS) 2003–2006	\$1.3 billion (2003–2006 average)	137,036 (2003–2006 average)	Covers income losses when farm income from current year is less than average farm income from previous years Intended to help producers protect their operations from declines in income	Provincial— Alberta, Ontario, Quebec, Prince Edward Island AAFC—all other provinces and territories
Agrilnvest (similar to NISA) 2007–2012	\$279 million (2007–2009 average) + \$563 million Kickstart (one- time payment in 2008)	140,894 (2007–2009 average)	Covers smaller income declines (15 percent or less), previously covered under CAIS Savings account matched by government funds—no proof of loss required to access funds Limited to 1.5 percent of allowable net sales ² Maximum payment is \$22,500 per producer.	AAFC, Quebec
AgriStability (similar to CAIS) 2007–2012	\$731 million (2007–2009 average)	109,870 (2007–2009 average)	Covers income declines greater than 15 percent, previously covered under CAIS Covers income losses when farm income from current year is less than average farm income from previous years Farm income calculations are based on individual producer data and income tax information.	Provincial— Alberta, Ontario, Quebec, Prince Edward Island (British Columbia and Saskatchewan as of January 2010) AAFC—all other provinces and territories

¹Based on program year. The processing of producer applications and payments occurs after the program or growing year is complete.

Source: Agriculture and Agri-Food Canada

Allowable net sales means eligible agricultural commodity sales net of allowable expenses. Eligible agricultural commodities are livestock and/or crops specified by the Department.

The Department also implements one-time programs to address specific industry problems. One such program is the Tobacco Transition Program, which the federal government announced in 2008. Efforts have been undertaken previously, through two federal programs in 1987 and 2005 as well as complementary provincial programs, to help farmers exit from tobacco farming and improve the viability of remaining tobacco farmers.

Focus of the audit

- Our audit included three programs involving payments to producers—AgriInvest, AgriStability, and the Tobacco Transition Program. We examined whether the Department followed a risk-based approach in developing and implementing its payments to producers programs—in particular, whether it
 - followed a risk-based, lessons-learned approach in developing and improving the programs; and
 - established clear accountability and monitoring practices in implementing the programs.
- The audit focused on the process followed and action taken to develop, implement, and continuously improve the programs, including use of lessons learned, identification of risks and management of those risks, and use of program evaluation and strategic review findings. This included reviewing the Department's progress in carrying out its commitments in response to the recommendations from our audit of the CAIS program in 2007. We also looked at the Department's use of input from producers, partners, and stakeholders to improve program design and administration. As part of our audit, we looked at the process followed in transferring administration of AgriStability to the provinces of British Columbia and Saskatchewan.
- 3.10 More details on the audit objectives, scope, approach, and criteria are in About the Audit at the end of this chapter.

Partners-Provinces, territories, and service delivery providers, such as financial institutions (banks and credit unions).

Stakeholders—Industry groups representing agricultural sectors, such as dairy farmers and pork producers.

Observations and Recommendations

Improving program design

- 3.11 Stabilizing farm incomes is a shared responsibility between the federal government, provinces, and territories. A key policy outcome of the Growing Forward Framework Agreement is that farm income support programs are to be timely, responsive, and predictable. Changes to program design need to be negotiated with the provinces and territories, and requirements for administering the programs are included in the Agreement and its Program Guidelines.
- 3.12 The Treasury Board's Integrated Risk Management Framework requires that plans, processes, and products be developed through ongoing consultation with stakeholders who may be affected by an organization's decisions and actions. In our 2008 chapter entitled Managing Environmental Programming, we recommended that Agriculture and Agri-Food Canada prepare a schedule of review and consultation through the life of the Growing Forward Framework Agreement to ensure a smooth and timely transition to future policy frameworks. The Department agreed and indicated that it would also assess the strengths and weaknesses of past approaches.
- 3.13 We examined a number of initiatives carried out by the Department to improve the design of two producer income support programs, AgriStability and AgriInvest. These initiatives included industry consultation, a strategic review, producer surveys, and focus groups. Some of these initiatives were undertaken with the transformation of the Canadian Agricultural Income Stabilization (CAIS) program to AgriStability and AgriInvest. Other more recent initiatives have been carried out in preparing for the next income support framework—Growing Forward 2, to be implemented in 2013.
- 3.14 During the life cycle of the CAIS program (2004–2007 program years), the Department carried out the following initiatives in the redesign to AgriStability and AgriInvest:
 - The CAIS Task Team was formed to provide program options (2006).
 - Industry consultations were held (2006–07).

In addition, there was input from two joint government/industry standing committees—the National CAIS Committee and the National Safety Nets Advisory Committee.

- **3.15** To provide input to the development of Growing Forward 2, the Department carried out the following additional initiatives:
 - A survey was conducted to gather producer feedback on service (2009).
 - A survey was conducted on farm risks and how the farm income support programs are helping (2010).
 - Focus groups on service quality were held (2009–10).
 - A strategic review was conducted to address continuing pressures for program changes (2008–10).
 - As well, there has been ongoing input from a new joint government/industry committee—the National Program Advisory Committee.

Progress has been made on some design issues, but long-standing problems remain

- **3.16** Improved design. The CAIS Task Team proposed three program design changes, which were approved by federal/provincial/territorial ministers. These resulted in a more accurate assessment of producers' inventories (numbers of livestock and/or harvested crops on hand), improved payments to producers facing back-to-back losses, and an early partial AgriStability payment option for producers experiencing a regional or sector-wide disaster.
- 3.17 During the industry consultations held in the 2006–07 fiscal year, producers indicated that some portion of a producer's income loss should be replaced with a program similar to the earlier NISA-type program (producers' savings account deposits matched by government). The AgriInvest program was therefore implemented to replace the support previously provided by the CAIS program for the first 15 percent of income loss with a savings account program. Producer deposits are matched by contributions from the federal and provincial governments. AgriInvest amounts received by producers are more predictable and simpler to administer than the previous CAIS payments.
- 3.18 Delayed implementation of program. The Department planned to have an agreement with financial institutions in the fall of 2008, so that AgriInvest accounts would be in place by 2009. However, financial institutions were reluctant to take part in the program as presented, in part because producers could withdraw the funds at any time (which could limit the recovery of the costs of setting up AgriInvest bank accounts).

- 3.19 Financial institutions were also concerned that the Department might waive the producer deposit requirement, as it had done for the 2003 to 2005 CAIS program years. This would again limit cost recovery from account balances. In addition, the government proposed a new Information Technology (IT) transfer system that was not compatible with their systems, instead of using existing IT systems that were compatible. Given the economic climate at the time, the financial institutions were reluctant to incur the infrastructure costs to set up the accounts, only to have the deposit requirement waived and the program potentially end a few years later.
- 3.20 In addition, financial institutions found the Department's timeline for preparing to deliver the AgriInvest program unrealistic. As a result, the Department had to administer the AgriInvest accounts until financial institutions were ready to take them over. As of May 2011, more than one third of producer accounts, representing 12 percent of account balances, were still being administered by the Department and not by the financial institutions. For the first three program years of a five-year program, producers had different processes for participating in AgriInvest.
- 3.21 Despite the delay in implementing the program through financial institutions, producers benefited because they were not required to make a matching deposit. In 2008, producers received about \$563 million in AgriInvest Kickstart funds (Exhibit 3.1), with no matching deposit required. As well, for the 2007 program year, the government's share was provided, but the Department waived the deposit requirement for producers. For the 2008 and 2009 program years, a deposit by producers was required to obtain the government's matching funds.
- 3.22 Long-standing problems. The Department conducted two surveys and a set of focus groups in 2009 and 2010. Survey participants indicated that farm income support programs helped them to minimize financial risk. However, the survey reports indicated that for AgriStability,
 - users were less satisfied than users of other farm income support programs;
 - timeliness of payments to producers was a concern;
 - producers found that fulfilling program requirements was burdensome;

- barriers to producers applying to the programs were related to the complexity of the program, lack of payment predictability, and cost of preparing program applications; and
- program information was easy to find but difficult to understand.
- 3.23 Producers have previously raised similar concerns about the CAIS program. For complex programs like CAIS and AgriStability, where the payment is based on specific farm information over a number of years, there is an inevitable trade-off between program specificity and timeliness of payment. The more tailored the payment is to the farm operation, the more complex the calculation becomes and the longer it takes to process the application. The Department, with the provinces, has to find the balance between these trade-offs.
- 3.24 The Department informed us that it has received some input on these trade-offs from producer representatives. Obtaining this feedback is important for the Department to be aware of the priority of producers' concerns and to help manage producers' expectations for program modification.
- The Department has presented various options to address longstanding concerns of producers to the federal/provincial/territorial working groups that oversee the income support programs. Despite the initiatives to improve program design, efforts to address the longstanding issues of program complexity, predictability, and timeliness of payments to producers have had only limited success. It may be necessary to further engage the agricultural sector industry representatives and producers to ensure that trade-offs between targeting and timeliness are understood.
- 3.26 Another long-standing problem is understanding program objectives and responsibilities for managing farm income risks. From 2008 to 2010, the Department conducted a strategic review to address pressures from producers and industry for program improvements. The review found a lack of clarity in the roles and responsibilities for producers, industry, and government relative to farm income risk management. It also found that objectives for income support programs needed to be clarified. The review concluded that these factors may have contributed to the current discontent and differing expectations of producers.
- In summary. We found that the Department is aware of and has identified concerns with its income support programs. Federal provincial/territorial governments have made some improvements to program design—for example, by introducing Agrillovest. However,

long-standing concerns remain, including unclear program objectives, lack of timely access to program funding, and program complexity that affects producers' ability to reasonably predict payment amounts. Department officials have indicated that they are aware of these concerns and are discussing their implications during their consultation with industry and provincial/territorial partners for Growing Forward 2 programs.

Recommendation. Agriculture and Agri-Food Canada should work with provinces and territories to help increase producers' and stakeholders' understanding of the objectives and trade-offs of income support programs and to clarify government's and producers' responsibilities for managing farm risks.

The Department's response. Agreed. The current suite of programs was designed with industry to respond to the needs of producers. In conjunction with provincial and territorial governments, the Department continues to consult extensively with industry in the development of programming, most recently through two rounds of industry engagement on the next generation of the agricultural policy framework (Growing Forward 2). Through future rounds of broadbased engagement, as well as more targeted sessions with producers, their associations, and formal mechanisms such as through the National Programs Advisory Committee, the Department will continue to gain a common understanding with producers of the respective roles in managing risk, of the objectives of programming, and of the inherent trade-offs within programs. This recommendation will be fully implemented with Growing Forward 2 in April 2013.

3.29 Recommendation. Agriculture and Agri-Food Canada should work with service delivery partners to understand their challenges and develop and monitor realistic implementation timelines for future income support programs.

The Department's response. Agreed. In delivering programs, the Department's objective is to ensure that the intended benefits of programming are available to participants in a timely manner. Under the Growing Forward 2 policy framework, the Department will actively engage service delivery partners in the process of developing and implementing income support programs. Officials will work with these partners to ensure that challenges are identified and documented, and that workable and timely solutions are developed to secure appropriate service delivery for producers. As it did with the delivery of AgriInvest, the Department will also ensure that contingency plans are in place so that producers have access to program benefits despite challenges that

may arise with the intended delivery arrangement. By relying on such contingency plans, the Department was able to ensure that producers had access to AgriInvest funding, although the infrastructure with financial institutions was not in place for the 2007 and 2008 program years. This recommendation will be fully implemented with Growing Forward 2 by April 2013.

Improving program administration

3.30 In our 2007 audit, we raised concerns about Agriculture and Agri-Food Canada's administration of the CAIS program. The Treasury Board's Framework for Service Improvement requires departments to have systems in place aimed at continuous improvement. As well, the Treasury Board's Risk Management Policy requires departments to analyze and assess the risks identified and to implement cost-effective prevention, reduction, or avoidance control measures. We examined the Department's progress on previous audit findings, and its monitoring of evaluation recommendations, risk management strategies, and causes of delays to timely processing.

The Department has made progress on previous audit findings

- 3.31 We found that the Department has made progress on some key administrative issues raised in our 2007 CAIS audit. At that time, we noted that the Department's method of calculating payments (also referred to as benefits in the Department) was not clear to producers. Our current audit found that the Department has made several improvements to the Calculation of Benefit Statement, such as including a summary and explanation of changes to submitted application forms.
- 3.32 In 2007, we found that the Department's focus on overpayments to producers was not proportional to the risk of producer underpayments. In our current audit, we found that the Department has made enhancements to its policies and procedures to better balance the identification and management of over- and underpayments, including improvements to the automated validation of applications and the audits of producers.
- 3.33 For AgriStability, part of the Department's quality control system is to review samples of payments after they have been issued to assess whether payments have been accurately calculated. In our 2007 audit, we found that the accuracy rate was close to the performance target of 97 percent; our current audit found that the payment accuracy rate for the 2008 program year is close to 98 percent, exceeding the target.

3.34 The Department also reviews samples of AgriStability payments before they are issued to determine the error rate and correct the payments before issuing them. We found that pre-payment errors have decreased, from 12.3 percent in 2005 to 3.7 percent in 2008.

Monitoring of key planned actions needs improvement

- **3.35 Program evaluation.** An evaluation of the CAIS program was reported in 2007. The evaluation report noted that its scope was limited by the lack of recent performance information, by the lack of survey data to provide insights into producer feedback, and by other things.
- **3.36** As a result, the evaluation recommended a number of administrative improvements, such as the development of more timely performance information and data showing the link between income support programs and producers' ability to manage risks and be profitable and viable in the long term.
- 3.37 The Department established an action plan subsequent to the evaluation. All actions were to be completed by 2008; however, this was not achieved. We found a lack of systematic tracking of progress against the planned actions and little progress on some recommendations compared with others. For example, while the Department developed a sound performance measurement framework in August 2009 for the successor program AgriStability, it has made little progress in improving communication to producers on their farm risk management responsibilities.
- **3.38** Risk mitigation. We found that program risk assessments were prepared for AgriStability and AgriInvest. Identified risks included producer confusion about the transition from the CAIS program to AgriStability and AgriInvest, and impacts on the AgriInvest program related to potential delays in developing new computer systems.
- 3.39 We found that there was no formal mechanism to track actions against mitigation strategies at the program level, and clear dates for carrying out mitigation strategies were not specified. Some of the identified risks materialized, such as continued producer confusion about the payment calculation for AgriStability. Delineation of risk management activities and timelines as well as periodic monitoring of progress are essential to mitigating risks on a timely basis.
- **3.40** Recommendation. Agriculture and Agri-Food Canada should develop and implement formal tracking and reporting systems to ensure that key planned actions for AgriStability and AgriInvest are carried out as expected.

The Department's response. Agreed. As a matter of practice, we work with provinces and territories to monitor, assess, and evaluate programs with a view to continuous improvement. The development of farm income support programs under the current Growing Forward Framework Agreement was informed by audits, evaluation, reviews, and assessments. As this type of work is undertaken for the next framework agreement, officials will implement a formal system to track documents to demonstrate the actions taken to address the recommendations, proposed actions, and risk-mitigating strategies that are carried out. This recommendation will be fully implemented with Growing Forward 2 by April 2013.

Further work is needed to improve the timeliness of payments to producers

- 3.41 AgriStability. The Department established a service standard for processing 75 percent of applications within 75 calendar days of receiving a complete application. Calculation of processing time does not start until the Department has received a completed program application, the required fees, and the relevant information from the Canada Revenue Agency. The Department has yet to meet its time standard for AgriStability payments, although there has been improvement over time. According to how the Department reports its performance against the service standard, its reported performance improved significantly from 38 to 66 percent, from the 2005 to the 2008 program year.
- 3.42 However, we noted that the Department publicly reports only on applications processed in determining its success in meeting the service standard. If it included the backlog of applications that have not yet been processed, its monthly success rate would drop. For example, in January 2011, 23 percent of processed applications for the 2009 program year met the 75-day standard. However, when unprocessed applications already beyond the 75-day standard were included, only 11 percent met the 75-day service standard.
- 3.43 We found that it could take up to two years for a producer to receive a payment, subsequent to an income loss. A recent analysis of payment timeliness conducted by the Department shows that 55 percent of producers are paid within 9 months following the year of loss, and 85 percent are paid within 19 months of the year of loss. The Department has completed some analysis to identify the causes of payment delays. However, it has not systematically followed up on the causes of delays and identified remedies to accelerate payment timeliness.

- To provide more timely support, the Department provides an interim AgriStability payment option. This provides earlier access to 50 percent of the estimated payment. However, use by producers has been low at 5.2 percent for the 2009 program year and 1.6 percent for the previous year. Furthermore, we found that the majority of interim AgriStability payments were not being processed within the Department's 30-day time standard. Despite this delay, the early AgriStability payment mechanism has been helpful in assisting some producers—for example, hog producers—in dealing with a sector-wide disaster (for example, the H1N1 virus and trade barriers to Canadian exports).
- 3.45 AgriInvest. Providing timely and predictable income support was a key reason for implementing AgriInvest. The application process for AgriInvest requires the producer to submit an application and, once it is approved, deposit funds in the account. These funds are then matched by the Department. Since the program was introduced in 2007, performance reports have not included information on payment timeliness or accuracy for AgriInvest. Without this information, the Department does not know whether AgriInvest payments to producers are timely.
- Recommendation. Agriculture and Agri-Food Canada should analyze processing of payments for AgriStability and AgriInvest in a more systematic manner and follow up on remedies to improve the timeliness of payments to producers.

The Department's response. Agreed. The Department is aware of the concerns about the timeliness of program payments. Leading up to the implementation of the current suite of programs, the Department reviewed potential approaches to improving the timeliness of payments in a number of venues with industry, as well as with provincial and territorial governments. The Department will more systematically review the design of income support programming as part of Growing Forward 2 discussions and will analyze its payment processes to improve the timeliness of processing of payments. In that regard, the recent implementation of an updated application processing system will provide the Department with the capacity to produce more systematic reporting on application processing. The Department will use the reporting capacity to further improve the timeliness of producer payments. This recommendation will be fully implemented with Growing Forward 2 by April 2013.

Monitoring federal/ provincial delivery

- 3.47 The Growing Forward Framework Agreement allows either federal or provincial administrations to deliver the AgriStability program. In accordance with the Treasury Board's Directive on Transfer Payments, departments are to ensure that delivery organizations or provinces are able to deliver federal programs and that agreements include written accountabilities that are monitored.
- **3.48** A number of provinces (Alberta, Ontario, Quebec, and Prince Edward Island) administered the CAIS program and subsequently the AgriStability program when it came into effect. They delivered about 60 percent of the AgriStability payments.
- 3.49 In October 2009, the Government of Canada approved funding to transfer the administration of AgriStability to British Columbia and Saskatchewan. The provinces indicated that they could provide better and more efficient service due to their knowledge of and proximity to producers. By December 2009, agreements with the two provinces were signed and producers were formally advised of the transfer. As of January 2010, the two provinces assumed responsibility for processing all applications in 2009 and subsequent program years. As a result, about 88 percent of AgriStability payment dollars are now delivered by the six provinces, and Agriculture and Agri-Food Canada delivers the remaining 12 percent of payment dollars to the other provinces.
- 3.50 We examined the transfer of the administration of the AgriStability program to the provinces of British Columbia and Saskatchewan, and whether financial and performance reporting requirements for both AgriStability and AgriInvest were met.

Transfer of AgriStability administration was sound, but monitoring responsibilities were not clear

- 3.51 Transferring AgriStability administration. We examined whether the Department ensured that the provinces of British Columbia and Saskatchewan had the capacity to deliver the program. Provinces were required to formally express interest in the delivery of AgriStability and then to present a business case to support their request. British Columbia submitted its business case in February 2009 and Saskatchewan in May 2009.
- 3.52 We found that the Department and provinces consulted extensively on the business cases to ensure that they had an understanding of their responsibilities in delivering the AgriStability program. The provinces engaged third parties to review their business cases. The Department analyzed the provincial business cases and the

Business case—Within a Government of Canada context, a business case is a proposal by an organization seeking approval for an initiative or project. It provides the information necessary to make an informed decision about whether to proceed. It is also the basis against which outcomes will be compared and evaluated.

third-party reviews of them. It also ensured that the provinces had the capacity to deliver the programs—for example, it ensured that the provinces hired and trained sufficient numbers of staff to successfully deliver the AgriStability program.

- 3.53 The provinces committed to improving customer service and reducing administrative costs over time. These commitments included
 - improved collection of customer service feedback,
 - reduced administrative costs,
 - improved communication with clients, and
 - audits of payments to producers conducted by provinces.
- Monitoring provincial commitments. The Department reviews administration and program costs to verify its 60 percent share of overall costs. However, we found that roles and responsibilities were not clear for post-transfer monitoring of all the commitments made by the provinces. It was not clear whether the provinces or the federal government should be reporting on these commitments and whether reporting should be only internal or also to the public.
- 3.55 Recommendation. Agriculture and Agri-Food Canada should add, to its future business case requirements, the need for a proposal from the provinces on whether the federal government or provincial governments will monitor and report on commitments in the business case.

The Department's response. Agreed. The Department will clarify how the monitoring and reporting of key provincial commitments (not already covered by existing mechanisms) should be addressed in any future business cases.

Audit and financial reporting requirements were substantially met

- 3.56 The Growing Forward Framework Agreement includes some monitoring provisions that enable each of the parties to confirm that the program is being administered according to the terms and conditions of the Agreement. These include preparing audited financial reconciliations of program payments and administrative expenses and carrying out compliance audits of provincial administrators.
- 3.57 We found that federal and provincial administrators had completed the audited reconciliations of program payments and administrative costs for the year ended 31 March 2009 within or

close to the time limit stipulated in the Growing Forward Framework Agreement.

3.58 The last time the Department carried out compliance audits of all program delivery administrators was for the 2005 CAIS program year. The Department told us that starting in the 2010–11 fiscal year, it planned to synchronize AgriStability compliance audits with audits of another federal farm program also administered by the provinces. Plans to audit one to three provincial administrations per year mean that, for some provincial administrators, there could be a six- to seven-year gap between compliance audits. Potential problems in program administration may not be known for many years, thereby preventing timely improvements to current and future programs.

Overall program performance is not publicly reported

- 3.59 The Department is delivering about 12 percent of program payments for AgriStability—a forecasted \$100 million for the 2010 program year, while the provinces are delivering the remaining 88 percent—about \$705 million. The Department delivers payments for AgriInvest in all provinces except Quebec. It is delivering \$254 million while Quebec is delivering about \$35 million (about 12 percent).
- 3.60 The Growing Forward Framework Agreement was signed by all provinces. According to the Agreement, each party is to be subject to public scrutiny, and for reporting purposes, its work must be managed in a manner that is open and transparent to the public. However, the Agreement does not specify the nature and frequency of performance information to be shared by the parties to the Agreement, or the type of information to be reported on publicly.
- 3.61 Despite these requirements not being in the Growing Forward Framework Agreement, Agriculture and Agri-Food Canada has made progress in designing a performance measurement framework. The Department's new performance measurement framework for farm income support programs has several performance indicators for AgriInvest and AgriStability. These include some important outcome measures, such as the extent to which income support programs respond to producer income losses. The Department and the provinces have agreed to the performance measurement framework, and it has been shared with a joint government/industry committee. Agreement still needs to be obtained with the provinces on some service standards for public reporting.

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- 3.62 The Department has collected and reported internally on performance information on agreed-upon service standards. However, there was an extensive delay in reporting overall results internally. Performance results for a program year cannot be reported until processing of applications is complete. Due to delays in application processing, the first internal performance report was not released until April 2010 for the 2007 program year. Performance results for the 2008 program year were reported in January 2011.
- 3.63 Given that the performance measurement framework has not yet been fully implemented, the Department does not provide information to the public about overall performance in administering AgriStability, including processing time, accuracy, and administrative cost efficiency. However, it does provide some overall information on producers participating in the program, such as program participation by size of farm and commodity type. Our recommendation is found at paragraph 3.66.

The Department is inconsistent in reporting on its performance to Parliament

- 3.64 We reviewed the Department's departmental performance reports and associated supplementary tables for the last three fiscal years (2007–08 to 2009–10) related to the CAIS/AgriStability Program to assess whether program results have been consistently identified.
- 3.65 We found that the reporting of targets and actual results was inconsistent, making year-to-year comparisons very difficult. Some targets and results were included in some years but not in others. Some of the inconsistency was due to the introduction of new programs under the Growing Forward Framework Agreement and changes in government-wide reporting requirements. The Department informed us that it will consistently report on its new performance measurement framework in the future.
- **3.66** Recommendation. Agriculture and Agri-Food Canada should work with the provinces to finalize and fully implement the agreed-upon performance measurement framework and to improve the completeness and timeliness of reporting to Parliament and the public on income support programs.

The Department's response. Agreed. The Department is committed to measuring and reporting on program performance and has developed an income support programs measurement framework with the provinces and territories to do so. The Department will refine the framework and leverage it in its departmental performance reporting

so that the reports are consistent and provide Parliament and the public with a complete view of program performance. This recommendation will be fully implemented with Growing Forward 2 by April 2013.

Managing the Tobacco Transition Program

3.67 Agriculture and Agri-Food Canada has frequently had to respond to an agricultural need by means of a one-time program. Particular and tailored strategies are therefore needed to deal with the unique challenges posed by this type of program.

Flue-cured tobacco—Tobacco that is cured in a kiln with a flue for external heat. This gives the tobacco a unique flavour.

3.68 Our audit examined one such program—the Tobacco Transition Program. This program is not an ongoing farm income support program. It was created to address the severe decline in demand for flue-cured tobacco from southern Ontario, which is the primary region in the country for producing flue-cured tobacco.

Quota—A limited quantity of a particular commodity that is authorized to be produced—in this chapter, the authorized amount of tobacco that can be grown.

- 3.69 The Ontario Flue-Cured Tobacco Growers' Marketing Board (Tobacco Marketing Board) was established in 1957 under provincial jurisdiction, as an entity authorized by Ontario law to regulate the sale of flue-cured tobacco leaf. The Board determined the price at which flue-cured tobacco would be sold to manufacturers, and it controlled the amount of flue-cured tobacco that could be grown through a quota system (at that time farmers were given a quota (pounds) for flue-cured tobacco production).
- 3.70 With declining production, the control of producers' entry/exit into the sector, and production and marketing of tobacco through a quota system, was no longer seen as the most appropriate way to manage production in the tobacco sector. Repealing the quota system and providing transition assistance would help to further rationalize the industry and allow tobacco producers to negotiate the price of their tobacco, similar to other agricultural commodities.
- **3.71** In 2008, the federal government announced the Tobacco Transition Program (TTP). The program had three objectives:
 - Remove the supply-managed quota system and implement a licensing system.
 - Facilitate the transition of Ontario flue-cured tobacco producers to exit the tobacco industry.
 - Improve the viability of remaining and future tobacco producers in southern Ontario.
- **3.72** The Tobacco Marketing Board delivered the TTP to producers on behalf of the Department. Under this program, tobacco producers

who agreed to leave the industry were paid \$1.05 per pound of quota. The Tobacco Marketing Board paid out a total of \$284 million by May 2009. The provincial government did not contribute funds to the TTP.

- 3.73 About 1,000 quota holders received payment under the TTP, and more than half were not active tobacco producers at the time. In 2008, 2009, and 2010, there were 446, 118, and 251 active tobacco producers, respectively.
- 3.74 The terms of the TTP required the Tobacco Marketing Board to remove the quota system and replace it with a licensing system. A licensing system does not limit the amount of tobacco that a producer can grow. Rather, to obtain a licence, a producer of flue-cured tobacco requires a contract of sale with a licensed buyer.
- 3.75 According to the Treasury Board's Integrated Risk Management Framework, departments are to apply risk management and lessons learned in program design and implementation. In addition, in accordance with the Treasury Board's Directive on Transfer Payments, departments are to ensure that external organizations are able to deliver federal programs and that agreements include written accountabilities that are monitored.
- The Tobacco Transition Program was developed and delivered within a short time frame. The Department received authority to enter into negotiations with the Province of Ontario in July 2008. The government announced the program publicly on 1 August 2008. Payments to producers were to be made by 1 May 2009. It was a challenge to establish design and delivery teams, obtain the appropriate authorities, develop the Funding Agreement with the service provider, and deliver the program in such a short time frame.
- 3.77 In addition, producers needed to be informed of the program details early to make important business decisions on their participation and on whether they should grow tobacco that year. Greenhouses need to be seeded in March, and tobacco seedlings are planted in the field in early May. Producers had to apply to the TTP by 23 March 2009.
- We examined the Department's risk assessment for the TTP. We also reviewed the Canada-Ontario Tobacco Board Funding Agreement (Funding Agreement) for the program. We reviewed correspondence between the Department and the Tobacco Marketing Board, program information to recipients and the public, and other departmental

documentation. Our recommendations for this program appear at paragraphs 3.82 and 3.91.

Key risks in program development were not considered

- 3.79 The Department did not conduct a thorough risk assessment of the Tobacco Transition Program. However, it carried out various actions to manage risks as they arose. It initially identified only one risk related to the TTP—that the quota system for flue-cured tobacco might not be removed and replaced by a licensing system within the required time frame. We did not see evidence that the importance of other risks was recognized prior to developing and signing the Funding Agreement in February 2009. Examples of other important risks are the following:
 - Inappropriate quota transfers. For the previous Tobacco Transition Assistance Program in 2005, tobacco farmers were not allowed to transfer their quota once the government announced the program. Transferring quota could allow someone who was never involved in tobacco farming to obtain the transition assistance payment, while the original quota holder continues to farm tobacco. The Department did not anticipate this risk or the extent to which it could occur.
 - Confusion about program terms. Another key risk that was not identified at the outset was confusion about program terms among recipients and the Tobacco Marketing Board. Throughout program implementation and afterwards, the Department responded to many complaints and queries from producers, lawyers, and others. The majority related to the business arrangements that TTP recipients could enter into for tobacco production and to the eligibility rules to obtain a licence to grow tobacco. The Department was still clarifying program terms for acceptable business arrangements in May 2009.
- **3.80** As well, the Department did not develop a formal risk register to identify and monitor risks during delivery of the program for follow-up on actions. However, it reacted quickly to address problems, to the extent possible, when they arose.
- **3.81** The lack of a thorough risk assessment and associated risk mitigation strategies had significant consequences:
 - Key program terms were not defined on a timely basis for producers and the Tobacco Marketing Board.
 - Inappropriate quota transfers took place and had to be reversed.

Transferring quota—The transfer of tobacco growing rights for quota holders to other individuals.

- The Department was successful in controlling some, but not all, business arrangements.
- Unnecessary confusion about acceptable business arrangements persisted, such as the type of arrangements that were allowed between TTP recipients and tobacco producers, including close relatives.
- **3.82 Recommendation.** For future one-time payment programs, Agriculture and Agri-Food Canada should conduct a thorough risk assessment during program development and maintain a risk register to support corrections throughout program delivery.

The Department's response. Agreed. The Department recognizes the need to conduct thorough risk analysis and develop mitigation strategies commensurate with program risks when implementing one-time payment programs. Consistent with the Policy on Transfer Payments, the Department is adopting a risk-based management approach to program design and implementation. Additional guidance and tools are under development to guide the development of program risk registers and ongoing risk management practices. This recommendation will be fully implemented by December 2012.

The funding agreement between the Department and the Tobacco Marketing Board was not clear

- 3.83 The Canada-Ontario Tobacco Board Funding Agreement did not provide clear expectations to the Tobacco Marketing Board on its administration of the Funding Agreement. In particular, it did not prevent quota transfers, and it was also not explicit about the types of relationships allowed between TTP recipients and future tobacco producers so that the intent of the program would not be undermined. The Department of Finance and the Treasury Board of Canada Secretariat recommended the addition of wording to control transactions between related individuals. However, Agriculture and Agri-Food Canada used very broad wording when it drafted the Funding Agreement, which was subsequently approved by the government.
- 3.84 Quota transfers. In March 2009, the Department became aware that a large number of quota transfers to non-quota holders were being exercised. It received complaints that these quota transfers were being done to bypass the TTP conditions. In response to these complaints as well as evidence that tobacco producers were transferring quota to non-farming family members, the Department directed the Tobacco Marketing Board to scrutinize all quota transfers and to deny a licence

to anyone whose actions could undermine the purpose and intent of the transition program. The number of quota transfers was reduced from 336 to 22, and quota holders incurred additional legal and accounting expenses in reversing the quota transfers.

- **3.85** Business arrangements. On 9 April 2009, the Department attempted to prevent the Tobacco Marketing Board from allowing certain types of business arrangements, including the following:
 - TTP recipients working on their own farm as employees;
 - independent children of TTP recipients renting their parents' land and infrastructure, and obtaining a licence to grow tobacco; and
 - TTP recipients loaning money to a licensee or co-signing at a bank for a loan for a licensee.

Without clear wording in the Funding Agreement, the Department could not impose its interpretation of the wording on the Tobacco Marketing Board. Therefore, the Department had to reverse its position on these issues on 7 May 2009. This led to additional confusion among producers.

The series of events listed in Exhibit 3.2 shows that the Department did not adequately prepare for the range and type of risks that might affect a program of this nature.

Follow-up initiatives were undertaken

- 3.86 External audit. After the TTP was implemented, the Department engaged external auditors to ensure that the TTP recipients, as well as the Tobacco Marketing Board, had complied with the obligations in the Funding Agreement. The external auditors ensured that the quota system was removed and verified the amount transferred from the Department to the Tobacco Marketing Board. In addition, they reviewed documents related to business arrangements with TTP recipients.
- 3.87 The external audit found that the Tobacco Marketing Board "did not appear to have issued licences to TTP recipients, their spouses or dependent children." In addition, the external auditors found that 13 (8 percent) business arrangements in 2009 and 56 (15 percent) in 2010 did not appear to be at fair market value. As well, 11 producers did not respond to the auditors' phone calls requesting further information.

Exhibit 3.2 Agriculture and Agri-Food Canada did not adequately prepare for the risks that might affect a program such as the Tobacco Transition Program

Action	Date	Action details
The Department announced the Tobacco Transition Program (TTP).	1 August 2008	The Department issued a fact sheet announcing the TTP and stating that producers who accepted transition assistance would not be able to re-enter tobacco production.
Producers submitted a petition requesting information on the terms and conditions of the program.	15 December 2008	As a result of the petition, the Tobacco Marketing Board arranged a meeting for its membership in February to help producers make informed choices. This was a joint meeting presented by the Department and the Tobacco Marketing Board.
The Department issued a news release/fact sheet.	5 January 2009	The Department provided updated information to producers on program funding, but it was unable, at that time in program development, to specify details on the terms and conditions to participate.
An information session with program details was held for tobacco producers.	18 February 2009	Producers asked a number of questions about their rights as TTP recipients and the rights of family members and relatives to obtain a licence. They also asked about transferring their quota to others. The Department and Tobacco Marketing Board presentation materials did not deal with quota transfers to non-quota holders.
The Department issued a fact sheet to producers to answer questions raised at the information session.	27 February 2009	The fact sheet indicated that the spouse and dependent children of a TTP recipient would not be entitled to a licence. However, an independent child (a child over 18 years of age) would be allowed to obtain a licence and sell tobacco. As well, a TTP recipient could become an employee of another tobacco farm if he/she did not have any direct or indirect interest in the ownership of that farm. The fact sheet was silent on quota transfers.
The Department received complaints about quota transfers.	3 March 2009	The Department became aware that a large number of quota transfers to non-quota holders were being exercised. It received complaints that these quota transfers were being done to bypass the TTP conditions.
The Department issued a letter to the Tobacco Marketing Board.	25 March 2009	In response to signs that tobacco producers were transferring quota to non-farming family members, the Department directed the Tobacco Marketing Board to scrutinize all quota transfers and to deny a licence to anyone whose actions could have the effect of undermining the purpose and intent of the transition program.
Quota transfers were reversed.	25-30 March 2009	The Department had to extend the date of application to the TTP program to 30 March 2009, to allow for reversal of the quota transfers. The number of quota transfers was reduced from 336 to 22.

Exhibit 3.2 Agriculture and Agri-Food Canada did not adequately prepare for the risks that might affect a program such as the Tobacco Transition Program (continued)

Action	Date	Action details
The Department issued a letter to the Tobacco Marketing Board.	9 April 2009	The letter was designed to direct the Tobacco Marketing Board to curtail close business relationships between TTP recipients and their relatives. This included, for example, TTP recipients working on their own farm as employees and children renting their parents' land and infrastructure and obtaining a licence to grow tobacco, when one or more parents was a TTP recipient. The letter was widely distributed to producers.
The Department issued a letter to the Tobacco Marketing Board.	7 May 2009	The Department changed its position on relationships outlined in the letter of 9 April 2009. It communicated to the Tobacco Marketing Board that such arrangements were allowed as long as the business relationship was at arm's length and, for example, rent or wages were at fair market value.
The Department received letters asking for clarity on relationship scenarios.	January to May 2010	Producers were still unclear on various relationship scenarios between TTP recipients and potential licence holders.

- 3.88 The external auditors noted a trend for TTP recipients to enter into business relationships with family members who have a licence for the production of tobacco. For example, they found that parents who were TTP recipients were leasing land and equipment to their non-dependent children, and adult children (over 18 years of age) who were TTP recipients were leasing land and equipment to their parents. A variety of other business relationships existed, such as between brothers, sisters, grandparents, and in-laws, all of which met the terms and conditions of the program under the Funding Agreement.
- **3.89** With respect to achievement of program objectives, the external audit concluded the following:
 - The objective to eliminate the quota system had been achieved.
 - The objective to improve the viability of remaining and future tobacco producers had been achieved (given that tobacco production more than doubled in 2010).
 - The objective to facilitate the transition of tobacco producers out of the tobacco industry was not as far advanced. Although TTP recipients were producing other crops, this production represented a small portion of their land. Recipients had also sought non-farm income, including renting their land and equipment to licensees to grow tobacco or becoming tobacco farm employees.

- **3.90** Lessons learned. The Department carried out a lessons-learned analysis of the program to identify the strengths and weaknesses of its design and implementation. Strengths noted included the following:
 - The Department obtained the appropriate approvals and money transfers in time.
 - The Department was responsive to producers' calls and contacted them to clarify rules.

Weaknesses noted included the following:

- Producers did not clearly understand the purpose of the program.
- Communication was unclear to the Tobacco Marketing Board about its role and how the program should be implemented.
- The Funding Agreement should have covered quota transfers.
- Greater attention was needed to anticipate issues that might arise.
- The Tobacco Marketing Board is a regulatory body of the Province of Ontario and represents the interests of all Ontario flue-cured tobacco producers. For the purposes of the TTP, this could be seen as being a conflict of interest.
- 3.91 Recommendation: Agriculture and Agri-Food Canada should
 - ensure an appropriate and timely follow-up on the findings of the Department's external audits of the Tobacco Transition Program (TTP), where the auditors raised concerns about business relationships or where producers did not provide the requested information; and
 - develop a cost-effective strategy for future monitoring of business arrangements between TTP recipients and licensees, to ensure their appropriateness.

The Department's response. Agreed. The Department has written to the Ontario Flue-Cured Tobacco Grower's Marketing Board to share the results of the audit findings and to set out expected next steps. Further to this follow-up, the Department will also develop a strategy for ongoing monitoring, on a cost-effective basis, of business arrangements between TTP recipients and licensees. This recommendation will be fully implemented by March 2012.

Conclusion

- **3.92** Our overall audit objective was to determine whether Agriculture and Agri-Food Canada followed a risk-based approach in developing and implementing its payments to producers programs.
- 3.93 We examined a number of initiatives carried out by the Department to improve the design of its producer income support programs, including industry consultation, strategic review, producer surveys, and focus groups. The Department, working with provinces and territories, has made progress on some design issues but long-standing concerns with AgriStability remain. These include unclear program objectives, lack of timely access to program funding, and program complexity that affects producers' ability to reasonably predict payment amounts. Department officials indicated that they are aware of these issues and are discussing their implications during their consultation with industry and provincial/territorial partners for Growing Forward 2 programs.
- 3.94 Implementation of AgriInvest through the financial institutions was delayed. For each of the first three program years of a five-year program, producers had a different process for participating in AgriInvest. Despite the delay in implementing the program through financial institutions, producers benefited. They received \$563 million in AgriInvest Kickstart funds with no matching deposit required. As well, for the 2007 program year, the Department waived the producer deposit requirement.
- 3.95 With respect to program administration, the Department has made progress in addressing issues raised in our 2007 audit, such as better managing underpayments to producers and payment accuracy. However, the Department has not systematically followed up on the causes of delays in payments to producers to accelerate payments. Although processing times for AgriStability payments have improved, the Department has not met its targets, and producers can wait up to two years to receive a payment subsequent to an income loss. In addition, the Department has not collected information on processing time for AgriInvest.
- 3.96 We found that the Department had carried out a risk assessment and identified risk mitigation strategies for AgriInvest and AgriStability. However, it needed to specify risk management activities and timelines and periodically monitor progress on activities.

- 3.97 While federal/provincial/territorial accountabilities for performance reporting were not specified in the Growing Forward Framework Agreement, a performance measurement framework has since been agreed to by all governments. The provinces now deliver 88 percent of AgriStability payments. Full implementation of the performance measurement framework is needed to provide an overall picture of performance against service standards to Parliament and the public. In addition, we found that the Department followed a sound process in assessing provincial capacity and transferring AgriStability administration to the provinces of British Columbia and Saskatchewan in 2010. However, it was not clear whether the federal government or the provinces would monitor and report on business case commitments.
- 3.98 The Department had to develop the Tobacco Transition Program within a short time frame and did not first conduct a thorough risk analysis. The agreement implementing the program did not provide clear terms and conditions to ensure that recipients would not enter into business arrangements that would undermine the intent of the program. The Department changed its interpretation of what was and was not allowed under the agreement a number of times, resulting in confusion for producers. As a result, the Department was successful in controlling some, but not all, business arrangements that it believed would undermine the intent of the program.
- For AgriStability and AgriInvest, we concluded that Agriculture and Agri-Food Canada followed a risk-based approach in developing and implementing its payments to producers programs, except for some needed improvements to analysis and follow-up and to public reporting on performance.
- 3.100 For the Tobacco Transition Program, we concluded that Agriculture and Agri-Food Canada did not follow a risk-based approach in developing and implementing the program.

About the Audit

All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by The Canadian Institute of Chartered Accountants (CICA). While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

Objectives

The overall audit objective was to determine whether Agriculture and Agri-Food Canada followed a risk-based approach in developing and implementing its payments to producers programs.

There were two sub-objectives; these were to determine whether Agriculture and Agri-Food Canada

- followed a risk-based, lessons-learned approach in developing and improving the programs; and
- · established clear accountability and monitoring practices in implementing the programs.

Scope and approach

The scope of the audit includes three payments to producers programs: AgriInvest, AgriStability, and the Tobacco Transition Program. It also includes the process of transferring administration of AgriStability to Saskatchewan and British Columbia.

The audit focused on

- the process followed to develop and improve the programs;
- the process followed for transferring administration of AgriStability to Saskatchewan and British Columbia; and
- the Department's accountability and monitoring in implementing the programs, including follow-up of our May 2007 chapter that covered the Canadian Agricultural Income Stabilization (CAIS) program.

The Department's internal auditors carried out some of the work on behalf of the Office of the Auditor General team. Specifically, they followed up on recommendations in our 2007 CAIS chapter, as they permitted to AgriStability. In addition, external auditors for the Department conducted follow-up work on the Tobacco Transition Program, as reported in our chapter. We took the steps required by CICA standards for reliance.

During the audit, we collected information through analysis of files, records, reports, and bilateral agreements. We also conducted interviews with the Department's management and staff responsible for the design and delivery of these programs, as well as interviews with third-party delivery organizations (that is, provincial government agencies, financial institutions, and other delivery partners) and stakeholders. The audit included trips to the Department's Farm Income Programs Directorate, located in Winnipeg.

We met with third-party delivery partners, stakeholders, and provincial government agencies; however, we did not audit their work.

Criteria

The criteria used in this audit apply to the time period in which the programs were delivered.

To determine whether Agriculture and Agri-Food Canada followed a risk-based approach in developing and implementing its payments to producers programs, we used the following criteria:		
Criteria	Sources	
Agriculture and Agri-Food Canada identifies risks specific to each program and the measures that will be used to manage these risks in a timely manner.	Integrated Risk Management Framework, Treasury Board, 2001	
The Department identifies and considers lessons learned in planning the new program.	Integrated Risk Management Framework, Treasury Board, 2001	
Where third-party delivery or provincial delivery was involved, the Department ensures that the delivery organization was suitable to deliver the program.	Directive on Transfer Payments, Treasury Board, 2008Policy on Transfer Payments, Treasury Board, 2000	
The Department uses input provided by partners, producers, and stakeholders to identify gaps in communication and to improve program design and operations.	Communications Policy of the Government of Canada, Treasury Board, 2006 Integrated Risk Management Framework, Treasury Board, 2001	
Program delivery and/or funding agreements between the Department and delivery organizations or provinces include written accountabilities that are monitored.	Directive on Transfer Payments, Treasury Board, 2008 Policy on Transfer Payments, Treasury Board, 2000	
The Department has systems in place aimed at continuous improvement.	A Policy Framework for Service Improvement in the Government of Canada, Treasury Board, 2000	
	Integrated Risk Management Framework, Treasury Board, 2001	

Management reviewed and accepted the suitability of the criteria used in the audit.

Period covered by the audit

The audit covered both the development and implementation of the programs. For AgriInvest and AgriStability, the audit covered the period between February 2006 and May 2011. For the Tobacco Transition Program, the audit covered the period between May 2004 and May 2011. Audit work for this chapter was substantially completed on 2 May 2011.

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Appendix List of recommendations

The following is a list of recommendations found in Chapter 3. The number in front of the recommendation indicates the paragraph where it appears in the chapter. The numbers in parentheses indicate the paragraphs where the topic is discussed.

Recommendation

Response

Improving program design

3.28 Agriculture and Agri-Food Canada should work with provinces and territories to help increase producers' and stakeholders' understanding of the objectives and trade-offs of income support programs and to clarify government's and producers' responsibilities for managing farm risks. (3.11–3.27)

Agreed. The current suite of programs was designed with industry to respond to the needs of producers. In conjunction with provincial and territorial governments, the Department continues to consult extensively with industry in the development of programming, most recently through two rounds of industry engagement on the next generation of the agricultural policy framework (Growing Forward 2). Through future rounds of broad-based engagement, as well as more targeted sessions with producers, their associations, and formal mechanisms such as through the National Programs Advisory Committee, the Department will continue to gain a common understanding with producers of the respective roles in managing risk, of the objectives of programming, and of the inherent trade-offs within programs. This recommendation will be fully implemented with Growing Forward 2 in April 2013.

3.29 Agriculture and Agri-Food Canada should work with service delivery partners to understand their challenges and develop and monitor realistic implementation timelines for future income support programs.

(3.11–3.27)

Agreed. In delivering programs, the Department's objective is to ensure that the intended benefits of programming are available to participants in a timely manner. Under the Growing Forward 2 policy framework, the Department will actively engage service delivery partners in the process of developing and implementing income support programs. Officials will work with these partners to ensure that challenges are identified and documented, and that workable and timely solutions are developed to secure appropriate service delivery for producers. As it did with the delivery of AgriInvest, the Department will also ensure that contingency plans are in place so that producers have access to program benefits despite challenges that may arise with the intended delivery arrangement. By relying on such contingency plans, the Department was able to ensure that producers had access to AgriInvest funding, although the infrastructure with financial institutions was not in place for the 2007 and 2008 program years. This recommendation will be fully implemented with Growing Forward 2 by April 2013.

Recommendation

Response

Improving program administration

3.40 Agriculture and Agri-Food Canada should develop and implement formal tracking and reporting systems to ensure that key planned actions for AgriStability and AgriInvest are carried out as expected. (3.35–3.39) Agreed. As a matter of practice, we work with provinces and territories to monitor, assess, and evaluate programs with a view to continuous improvement. The development of farm income support programs under the current Growing Forward Framework Agreement was informed by audits, evaluation, reviews, and assessments. As this type of work is undertaken for the next framework agreement, officials will implement a formal system to track documents to demonstrate the actions taken to address the recommendations, proposed actions, and risk-mitigating strategies that are carried out. This recommendation will be fully implemented with Growing Forward 2 by April 2013.

3.46 Agriculture and Agri-Food Canada should analyze processing of payments for AgriStability and AgriInvest in a more systematic manner and follow up on remedies to improve the timeliness of payments to producers. (3.41–3.45)

Agreed. The Department is aware of the concerns about the timeliness of program payments. Leading up to the implementation of the current suite of programs, the Department reviewed potential approaches to improving the timeliness of payments in a number of venues with industry, as well as with provincial and territorial governments. The Department will more systematically review the design of income support programming as part of Growing Forward 2 discussions and will analyze its payment processes to improve the timeliness of processing of payments. In that regard, the recent implementation of an updated application processing system will provide the Department with the capacity to produce more systematic reporting on application processing. The Department will use the reporting capacity to further improve the timeliness of producer payments. This recommendation will be fully implemented with Growing Forward 2 by April 2013.

Monitoring federal/provincial delivery

3.55 Agriculture and Agri-Food Canada should add, to its future business case requirements, the need for a proposal from the provinces on whether the federal government or provincial governments will monitor and report on commitments in the business case. (3.47–3.54)

Agreed. The Department will clarify how the monitoring and reporting of key provincial commitments (not already covered by existing mechanisms) should be addressed in any future business cases.

Recommendation

3.66 Agriculture and Agri-Food Canada should work with the provinces to finalize and fully implement the agreed-upon performance measurement framework and to improve the completeness and timeliness of reporting to Parliament and the public on income support programs.

(3.59–3.65)

Response

Agreed. The Department is committed to measuring and reporting on program performance and has developed an income support programs measurement framework with the provinces and territories to do so. The Department will refine the framework and leverage it in its departmental performance reporting so that the reports are consistent and provide Parliament and the public with a complete view of program performance. This recommendation will be fully implemented with Growing Forward 2 by April 2013.

Managing the Tobacco Transition Program

3.82 For future one-time payment programs, Agriculture and Agri-Food Canada should conduct a thorough risk assessment during program development and maintain a risk register to support corrections throughout program delivery. (3.67–3.81)

3.91 Agriculture and Agri-Food Canada should

- ensure an appropriate and timely follow-up on the findings of the Department's external audits of the Tobacco Transition Program (TTP), where the auditors raised concerns about business relationships or where producers did not provide the requested information; and
- develop a cost-effective strategy for future monitoring of business arrangements between TTP recipients and licensees, to ensure their appropriateness.
 (3.83–3.90)

Agreed. The Department recognizes the need to conduct thorough risk analysis and develop mitigation strategies commensurate with program risks when implementing one-time payment programs. Consistent with the Policy on Transfer Payments, the Department is adopting a risk-based management approach to program design and implementation. Additional guidance and tools are under development to guide the development of program risk registers and ongoing risk management practices. This recommendation will be fully implemented by December 2012.

Agreed. The Department has written to the Ontario Flue-Cured Tobacco Grower's Marketing Board to share the results of the audit findings and to set out expected next steps. Further to this follow-up, the Department will also develop a strategy for ongoing monitoring, on a cost-effective basis, of business arrangements between TTP recipients and licensees. This recommendation will be fully implemented by March 2012.



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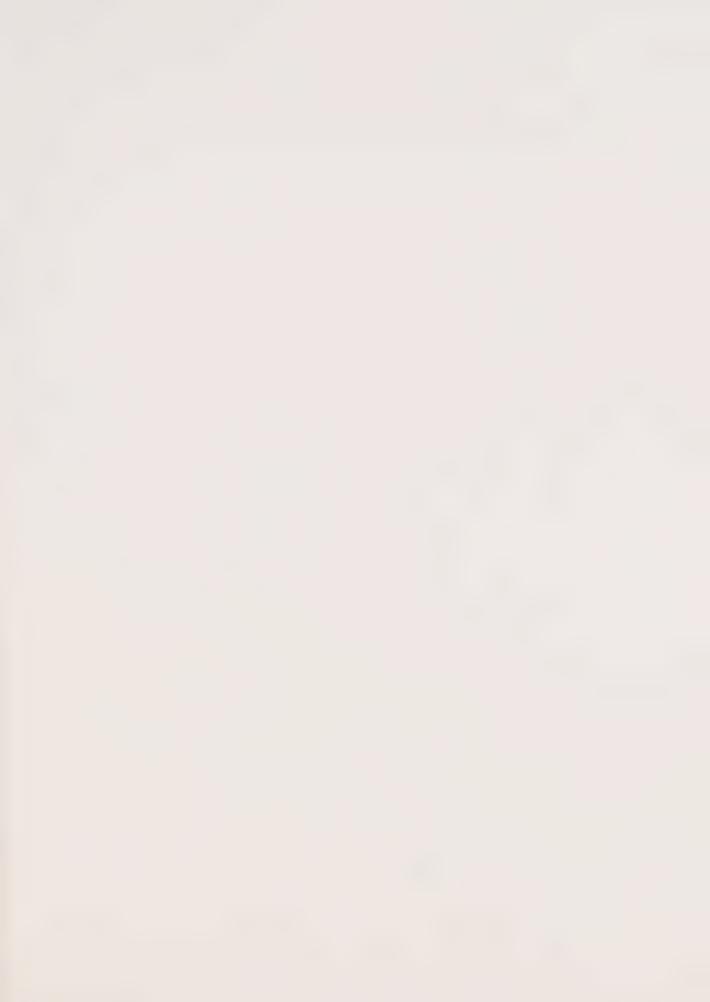
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Auditor General
of Canada
to the House of Commons

FALL

Chapter 4
Regulating Pharmaceutical Drugs—
Health Canada



Office of the Auditor General of Canada



2011



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Office of the Auditor General of Canada

The Fall 2011 Report of the Auditor General of Canada comprises Matters of Special Importance, Main Points—Chapters 1 to 5, Appendices, and five chapters. The main table of contents for the Report is found at the end of this publication.

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4

Regulating Pharmaceutical Drugs— Health Canada

Performance audit reports

This report presents the results of a performance audit conducted by the Office of the Auditor General of Canada under the authority of the Auditor General Act.

A performance audit is an independent, objective, and systematic assessment of how well government is managing its activities, responsibilities, and resources. Audit topics are selected based on their significance. While the Office may comment on policy implementation in a performance audit, it does not comment on the merits of a policy.

Performance audits are planned, performed, and reported in accordance with professional auditing standards and Office policies. They are conducted by qualified auditors who

- establish audit objectives and criteria for the assessment of performance;
- gather the evidence necessary to assess performance against the criteria;
- · report both positive and negative findings;
- · conclude against the established audit objectives; and
- make recommendations for improvement when there are significant differences between criteria and assessed performance.

Performance audits contribute to a public service that is ethical and effective and a government that is accountable to Parliament and Canadians.

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Regulating Pharmaceutical Drugs-Health Canada

Main Points

What we examined

Pharmaceutical drugs are mostly synthetic products made from chemicals. They are meant to improve the health and well-being of patients by helping to prevent and treat disease, reduce pain and suffering, and extend and save lives. Some higher-risk drugs, such as those used to treat diseases, require a prescription from a physician. Other lower-risk drugs, such as cough syrup and antacids, are sold without a prescription and are readily available to the public.

Health Canada, through the Food and Drugs Act, regulates the safety, efficacy, and quality of all pharmaceutical drugs for use by humans in Canada before and after the products enter the Canadian marketplace. The Department does this through a combination of scientific review. monitoring, compliance, and enforcement activities. It aims to ensure that the public has timely access to safe and effective pharmaceutical drugs and that those who need to know of safety concerns are informed.

We examined how Health Canada regulates clinical trials of new pharmaceutical drugs and reviews submissions seeking approval of new drugs for sale in Canada or of changes to drugs already on the market. We also examined how the Department monitors product safety and ensures that potential safety concerns are communicated to health care professionals and the public. In addition, we looked at how Health Canada enforces industry compliance with regulatory requirements governing the testing, production, and sale of drugs. We did not examine the soundness of the Department's regulatory decisions or the safety or efficacy of drugs.

The period under audit for this chapter was 1 January 2009 to 31 December 2010. Audit work for this chapter was substantially completed on 31 May 2011.

Why it's important

There are about 13,000 prescription and non-prescription drugs on the Canadian market. Pharmaceutical drugs play an important role in Canada's health care system and economy. In 2008, the Canadian retail market for prescription and over-the-counter drugs was valued at about \$28 billion, with prescription drug purchases accounting for almost 84 percent of total retail drug expenditures. According to IMS Brogan, a well-recognized provider of data to Health Canada and the pharmaceutical industry, about 505 million prescriptions were dispensed by Canadian retail pharmacies in 2010.

With an aging population, the role of pharmaceutical drugs is expected to grow as researchers come up with new drug therapies to replace earlier treatments or provide new options where no treatment existed before. Canadians who purchase and consume pharmaceuticals authorized for sale in Canada rely on the government and industry to monitor the safety of these products. Health Canada has a responsibility to help protect the public against undue health and safety risks from the use of pharmaceutical drugs.

What we found

- The Department does not take timely action in its regulatory activities, with the exception of its review of two types of drug submissions. In particular, the Department is slow to assess potential safety issues. It can take more than two years to complete an assessment of potential safety issues and to provide Canadians with new safety information.
- The Department received 4,400 drug submissions in 2009 and 2010. It has put in place processes and procedures to ensure that its drug reviews are consistent and high quality. However, it has not assessed whether these processes and procedures have been consistently interpreted and applied across its four review bureaus.
- Health Canada does not disclose information on drug submissions that it has rejected or information on the status of the drugs it has approved with conditions. In addition, the Department has not acted on its long-standing commitment to disclose more information about clinical trials it has authorized. This increases the risk that Canadians may be unaware of new treatment options or may unknowingly participate in an unauthorized trial.
- Health Canada's conflict-of-interest guidelines and Code of Conduct are consistent with government policy on conflict of interest. However, unlike another major regulator of pharmaceutical drugs and some federal departments that have developed conflict-of-interest requirements for specific work assignments, the Department has not determined what measures are necessary for its review activities.

The Department has responded. The Department agrees with all of our recommendations. Its detailed responses follow the recommendations throughout the chapter.

Introduction

Regulating pharmaceutical drugs in Canada

- 4.1 Each day, Canadians and their health care providers use pharmaceutical drugs (herein referred to as drugs) that have been approved by Health Canada to treat or prevent an array of diseases and disabling physical conditions. Enabling timely access to safe and effective drugs, and ensuring that these products remain safe and effective, is critical to improving and maintaining the health of Canadians.
- **4.2** Drugs are regulated under the *Food and Drugs Act*, which is administered by Health Canada. The Department defines pharmaceutical drugs as synthetic products made from chemicals, including
 - prescription and non-prescription drugs;
 - · disinfectants; and
 - products, such as sunscreens and antiperspirants, that are usually low risk.
- 4.3 There are about 13,000 drugs on the Canadian market, many of which are critical to high-quality health care. Canadians were expected to spend about \$31 billion on these drugs in 2010. According to IMS Brogan, a well-recognized provider of data to Health Canada and the pharmaceutical industry, about 505 million prescriptions were dispensed by Canadian retail pharmacies in 2010.
- 4.4 Under the Food and Drugs Act and its accompanying regulations, Health Canada, as federal regulator, is responsible for assessing and monitoring the safety and efficacy of drugs marketed in Canada. The Department carries out these responsibilities through various regulatory activities that are designed to evaluate and monitor the safety, efficacy, and quality of drugs before and after they are marketed. Some of the costs of these activities are shared with industry, but others, such as reviewing clinical trial applications and compliance and enforcement activities for clinical trials, are funded solely by the Department. In the 2009–10 fiscal year, Health Canada spent about \$80 million in direct program costs and employed approximately 700 full-time employees for drug regulation. The Department received about \$33 million in fees from the pharmaceutical industry during the same period.

Stakeholders in pharmaceutical drug safety

- **4.5** There are several important stakeholders whose participation in the regulatory system is critical to supporting the safe and effective use of drugs.
- 4.6 The Canadian public. Canadians rely on Health Canada to approve drugs of demonstrated safety, quality, and efficacy and to work with the pharmaceutical industry to disseminate safety and usage information that is accurate and up to date. Canadian volunteers participating in clinical trials also rely on the Department to verify that authorized trials are designed appropriately, so they are not exposed to unnecessary risks.
- 4.7 Health care professionals. Health care professionals play an important role in promoting the appropriate use of drugs. To provide the public with information on the risks and benefits of specific drugs, health care professionals rely on Health Canada and drug manufacturers to disseminate safety and usage information that has been officially approved and that is accurate and up to date.
- 4.8 Health care professionals can also play a role in monitoring the continued safety of approved drugs. They are often the first to become aware of serious adverse drug reactions, and this makes them a critical source of safety information. Health Canada asks them to pass on this information when it comes to their attention, either to the manufacturer or directly to the Department. By doing so, they contribute to the evolving knowledge of a product's risks and benefits.
- 4.9 Pharmaceutical industry. The legal responsibilities of the pharmaceutical industry are outlined in the Food and Drug Regulations. The regulations place significant responsibility on the industry to protect the health and safety of the public. For example, the pharmaceutical industry is required to obtain authorization from Health Canada before conducting clinical trials of unapproved drugs. In its drug submissions to the Department, the industry is required to provide evidence that a drug meets safety, efficacy, and quality requirements. After the Department has approved a drug for sale, manufacturers are required to report all serious adverse drug reactions to Health Canada and to maintain the quality of their product. Manufacturers are also responsible for communicating new safety information about their products to health care professionals and consumers.

Health Canada's regulatory approach

4.10 Health Canada's approach to the regulation of drugs focuses on well-defined points in the regulatory process that lead to a drug's marketing approval. However, after the Department has authorized a drug for sale, it has limited regulatory authority to require label changes that address new safety information or to require manufacturers to undertake additional post-market studies. Other regulators have greater post-market regulatory authorities. For example, the US Food and Drug Administration can legally require industry to propose labelling changes to reflect new safety information within 30 days of a request.

4.11 Health Canada's responsibilities include the following core activities:

- reviewing clinical trial applications, for clinical trials to be conducted in Canada;
- reviewing drug submissions from manufacturers for market authorization and for post-market changes;
- monitoring the safety of drugs in the Canadian market and communicating safety risks to health care professionals and the public, in collaboration with industry;
- enforcing the pharmaceutical industry's compliance with regulations, including those related to clinical trials, drug manufacturing, and the reporting of adverse drug reactions.

Exhibit 4.1 includes an overview of the regulatory process.

Exhibit 4.1 Regulatory process for drugs in Canada

Source: Health Canada

Pre-Market

Pre-clinical studies

| Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studies | Clinical studie

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Focus of the audit

- **4.12** The focus of our audit was to determine whether Health Canada fulfilled its key responsibilities related to clinical trials, submission reviews, and post-market activities for the regulation of drugs.
- 4.13 We examined whether the reviews of clinical trial applications and pharmaceutical submissions were timely and whether the Department had established processes to support the timely, consistent, and high-quality review of drug submissions. We examined the steps the Department took to support the transparency of authorized clinical trials and its reviews, and the systems it implemented to manage potential conflicts of interest. We looked at how the Department monitored the safety of drugs in clinical trials and of drugs that had already been marketed, and whether it communicated safety concerns to health care professionals and Canadians in a timely manner. Finally, we examined the Department's methods for verifying the regulatory compliance of the pharmaceutical industry.
- **4.14** We did not examine authorized clinical trials to determine whether they were safe for the participants. We did not examine completed reviews of drug submissions to determine whether drugs approved by the Department were safe or effective or whether they were reviewed in a consistent manner. We did not examine the risks and benefits of marketed drugs.
- 4.15 More details about the audit objectives, scope, approach, and criteria are in **About the Audit** at the end of this chapter.

Observations and Recommendations

Regulating clinical trials

- 4.16 Clinical trials are experiments involving volunteer participants that are used to determine whether a drug is safe and effective and what side effects are associated with its use. Parties seeking to conduct clinical trials in Canada must submit a clinical trial application to Health Canada, except for clinical trials on drugs that are already on the market and are being tested to treat conditions for which they were authorized.
- 4.17 In 2001, the government revised the *Food and Drug Regulations* to strengthen protection for clinical trial participants. Health Canada also developed a national inspection program to verify that clinical trials conducted in Canada comply with these regulations, which were designed to protect the participant's safety and to generate high-quality

clinical data. The Department estimates that there are 4,000 active clinical trial sites (many sites are testing the same drug) in the country each year. If its inspectors identify significant non-compliance with the regulations, the Department can require immediate corrective action or, if necessary, revoke the trial's authorization.

Clinical trial applications and amendments were reviewed in a timely manner

- 4.18 In 2009 and 2010, Health Canada reviewed about 2,600 applications, and about 1,800 amendments to clinical trials, to assess whether the proposed trial or amendment posed undue risks to trial participants. Under the *Food and Drug Regulations*, if Health Canada does not review applications and amendments within 30 days, the trial can proceed or the amendment can be implemented by default. In addition, for selected clinical trial applications and amendments, the Department established a 7-day accelerated review target.
- 4.19 To determine the timeliness of its reviews of clinical trial applications and amendments in 2009 and 2010, we examined whether the Department was meeting the 30-day and 7-day timelines. We reviewed Health Canada's performance reports and assessed the completeness and accuracy of the data used to create these reports. We also examined management reports on program performance for the period under audit, analyzed data, and interviewed key officials. We found that the reviews of clinical trial applications and amendments were timely. The Department made all of its review decisions within the required 30-day period and met the 7-day target for selected clinical trial applications and amendments 90 percent of the time.

Additional steps are needed to strengthen a risk-based approach to oversee clinical trials

4.20 Monitoring adverse drug reactions. We examined whether Health Canada had established a risk-based approach to monitor adverse drug reactions in clinical trials. The Food and Drug Regulations require that clinical trial sponsors, such as drug companies and hospitals, inform the Department of all serious, unexpected adverse drug reactions for drugs being tested in Canadian clinical trials—regardless of whether the adverse drug reaction occurred at a trial site in Canada or in another country. The number of reported adverse drug reactions in clinical trials has increased dramatically over the past several years—43,000 in 2007, 88,000 in 2009, and 115,000 in 2010. According to the Department, about 95 percent of these reports are from foreign sources.

Adverse drug reaction—Any noxious and unintended response to a drug that is caused by the administration of any dose of the drug

- 4.21 Monitoring and assessing adverse drug reactions is important for ensuring that Canadians participating in clinical trials are protected and fully informed of potential safety risks. Monitoring the safety of the 700 drugs that are tested in clinical trials in Canada each year also provides the Department with information that can be used by drug reviewers, clinical trial inspectors, and officials responsible for monitoring the safety of marketed drugs.
- **4.22** We reviewed the Department's procedures to determine whether it had established a risk-based approach for monitoring and assessing adverse drug reaction reports.
- 4.23 We found that Health Canada receives all adverse drug reaction reports by fax or courier and manually enters them into its adverse drug reaction database for clinical trials. The process is labour intensive, and it uses resources that could otherwise be used to assess potential safety issues raised in these reports. A description of how the Department expects to address this issue can be found in paragraph 4.75.
- 4.24 Due to the significant number of drugs in clinical trials each year, the volume of reports received, and the labour-intensive process in place, it is important that Health Canada have a risk-based approach to monitoring drugs in these trials. Officials told us that assessment officers were monitoring drug reaction reports from the trials that pose the highest risks, such as early-phase clinical trials of drugs not previously tested and trials that include vulnerable populations (for example, children). However, at the time of our audit, there were no standard operating procedures for its monitoring activities to ensure that the Department consistently focused on the trials that posed the greatest risk.
- 4.25 When the Department receives adverse drug reaction reports that indicate there may be a safety issue with a drug, officials may choose to fully assess the adverse reaction and its relationship to the drug. The assessment may result in recommendations being issued to ensure that risks are communicated to and, if possible, reduced for clinical trial participants. While officials told us that hundreds of potential safety issues are awaiting assessment, we found that, at the time of our audit, the Department had not documented its criteria for prioritizing its assessment of these potential safety issues based on the risks posed to clinical trial participants.
- **4.26** Inspecting clinical trial sites. We examined Health Canada's approach to clinical trial inspections to determine whether its compliance and enforcement activities focused on those trials that

posed the greatest risk. The Department inspects Canadian clinical trial sites to verify that authorized trials comply with the *Food and Drug Regulations*, so the rights and safety of trial subjects are respected. It also verifies that the data generated by the trial site is of high quality, which is important because this data can be used to support submissions for new drugs seeking market authorization. The June 2010 draft Compliance and Enforcement Risk Evaluation Guide: An Approach to Decision Making, by the Health Product and Food Branch Inspectorate, specifies that compliance and enforcement activities associated with a regulated product or activity need to be appropriate and proportional to the risk posed.

- 4.27 To determine whether compliance and enforcement activities for clinical trials were risk-based, we reviewed the Department's clinical trial inspection strategy, its performance reports, and its procedures for inspections. We also reviewed finalized inspection reports for the six non-compliant clinical trials identified in 2009 and 2010. We assessed whether the Department obtained assurance that instances of non-compliance were addressed.
- **4.28** We found that Health Canada had developed a risk-based inspection strategy that included criteria to help inspectors determine which clinical trial sites to inspect. The strategy required that inspectors consider a number of potential risk factors, including the following:
 - number of clinical trials conducted at the site,
 - number of subjects enrolled in the specified clinical trial,
 - number of serious unexpected adverse drug reactions at the clinical trial site, and
 - observations made during past inspections.
- **4.29** However, we also found that Health Canada does not regularly collect all of the information necessary to assess these factors and to make comparative risk-based decisions. Because clinical trial sponsors are not required to submit up-to-date information on clinical trial sites, inspectors must call each site directly to find out the current status of the clinical trial site and the number of participants enrolled.
- **4.30** Officials told us that acquiring this information through direct contact with each clinical trial site is inefficient and that a significant amount of time is devoted to identifying potential inspection sites. Thus, inspectors have up-to-date information only for sites that they call and are unable to compare the risks posed by all sites.

- 4.31 Health Canada's strategy is to inspect two percent (that is, about 80 out of 4,000) of Canadian clinical trial sites in any given year. The Department told us that this target is consistent with the approaches taken by other major regulators. We found that the Department completed 52 inspections in 2009 and 50 in 2010. Officials indicated that the target (of 80 per year) could not be met because of a lack of resources and the reallocation of existing resources to other programs.
- 4.32 Since 2006, Health Canada has issued nine inspection reports with non-compliance ratings—six of which were issued in 2009 and 2010. We reviewed these six reports to determine whether the Department verified that instances of non-compliance with the *Food and Drug Regulations* were addressed. Depending on the nature of identified deficiencies, corrective actions may be required to protect the safety of clinical trial participants and to ensure the quality of clinical trial data.
- 4.33 For these six reports, we found that Health Canada took between 56 and 142 days to officially notify regulated parties that they were not compliant with the *Food and Drug Regulations* and to officially request corrective actions to address all identified deficiencies. The Department has not established timelines for issuing these notifications, but regulated parties are required to propose corrective actions within four weeks of receiving an official notification of non-compliance.
- 4.34 Health Canada also reviews the adequacy of corrective actions proposed by regulated parties, but it has not set timelines for this review, either. During our audit, the Department reviewed proposed corrective measures for two non-compliant inspection reports and took about 110 days for each review. Officials told us that, during this time, the Department requested and reviewed additional information provided by regulated parties.
- **4.35** Recommendation. Health Canada should strengthen its risk-based approach for monitoring and assessing clinical trial adverse drug reaction reports and for inspecting clinical trial sites, so potential safety issues are mitigated.

The Department's response. Agreed. The Department is strengthening its risk-based approach to monitor and assess clinical trial adverse drug reaction reports and clinical trial inspections. A detailed standard operating procedure and strategy guide has been developed to prioritize the review of individual adverse drug reaction reports. This approach was implemented on 4 July 2011.

The Department expects to have completed a review of the existing risk-based process for selecting clinical trial inspection sites by fall 2011. This review will be used to assess the effectiveness of the existing process and to inform the development, documentation, and implementation of an enhanced process.

4.36 Recommendation. Health Canada should establish timelines for officially notifying clinical trial sites of non-compliant ratings and for reviewing proposed corrective measures to verify compliance with the Food and Drug Regulations.

The Department's response. Agreed. The Department is currently reviewing and revising its existing standard operating procedure for conducting clinical trial inspections. This revised standard operating procedure will emphasize establishing timelines for key steps in the inspection process, including notification of non-compliant ratings and the review of proposed corrective measures. This work will be completed by 31 March 2013.

Authorized clinical trials were not disclosed publicly

- 4.37 We examined steps taken by Health Canada to support the transparency of authorized clinical trials. In 2004, the House of Commons Standing Committee on Health recommended that the Department create a "... public database that provides information on trials in progress, trials abandoned and trials completed." In its 2007 Blueprint for Renewal II: Modernizing Canada's Regulatory System for Health Products and Food, the Department committed to enhancing public access to clinical trial information. Without this information, Canadians with life-threatening diseases may not become aware of trials that could offer new treatment options, and may not be able to verify whether the Department has authorized advertised trials.
- **4.38** We found that, despite commitments to increase the transparency of authorized clinical trials, the amount of information Health Canada made available to Canadians had not changed. There remains no definitive, publicly accessible source of information on clinical trials authorized by the Department.
- **4.39** For example, in 2008, Health Canada became aware of an unauthorized clinical trial when it was contacted by parents whose child was enrolled in the trial and who had concerns about the safety of the drug being tested. The physician running the trial was not based in Canada but was recruiting Canadian participants. According to files compiled by Health Canada during its review of the complaint,

advertisements for the trial claimed that the Department had authorized the trial. It was not until the parents contacted the Department with their concerns that they learned that it had not, in fact, authorized the trial. Electronic access to a listing of trials authorized by the Department would allow Canadians to consult official information, to verify claims made by other parties, and to make fully informed decisions.

- 4.40 In 1999 and 2004, parliamentary committees requested that Health Canada report annually on the findings of clinical trial inspections. Although openness and transparency are key aspects of its strategic and operational plans, the Department reported publicly only on its inspection activities in 2003 and 2004. For the past two years, it planned to publish a summary of its inspections on its website. At the time of our audit, a summary report on the clinical trial inspections conducted between 2002 and 2010 had been drafted but not published.
- **4.41 Recommendation.** Health Canada should fulfill long-standing commitments to enhance public access to information on authorized clinical trials, including the results of its clinical trial inspections.

The Department's response. Agreed. The Department will develop policies on enhancing public access to information on authorized clinical trials that respect privacy rights and legislation. Work began in 2011 and will be completed by 31 March 2013.

The Department commits to publishing periodic reports regarding clinical trial inspections, to provide stakeholders and the public with a summary view of its inspection findings by 31 March 2012.

Reviewing drug submissions

- 4.42 Health Canada received about 4,400 drug submissions in 2009 and 2010. The Department reviewed pre-market submissions to determine whether claims made by industry regarding a drug's safety, efficacy, and quality were supported by sufficient evidence.
- 4.43 Submissions for new drugs that comprise chemicals that have not been available for a long period of time (typically, prescription drugs) must include a significant amount of data from clinical trials. Submissions for drugs that have been available for longer and have established safety records (typically, over-the-counter drugs) do not usually require as much data.
- 4.44 Because the safety of each drug is not absolute, Health Canada must weigh the potential benefits and risks of those seeking access to the Canadian market to determine whether the risks are acceptable.

Post-market submissions are submitted when manufacturers wish to make changes to a label or manufacturing method for a product that has already been marketed.

Health Canada does not meet its own service standards for reviewing drug submissions

- 4.45 Health Canada reviews a variety of pre-market submissions to determine whether they include sufficient evidence to support the pharmaceutical industry's claims about drug safety, efficacy, and quality. In consultation with the pharmaceutical industry, the Department developed service standards for these reviews in 1996 (Exhibit 4.2).
- **4.46** To determine the timeliness of its review decisions, we examined whether the Department was meeting its own service standards for reviewing pharmaceutical submissions. We also examined management reports related to program performance for the period under audit, analyzed data, and interviewed key officials.
- 4.47 We found that in 2009 and 2010, Health Canada consistently met its service standards for timely reviews of supplemental new drug submissions. However, it did not consistently meet its service standards for reviewing most of the other submission types. The Department's performance for reviewing generic drugs, over-the-counter drugs that required a clinical review, and post-market change submissions was particularly poor (Exhibit 4.2).
- **4.48** We found that reviews completed in 2010 that did not meet service standards took significantly longer than the standard to complete. The following are examples:
 - Reviews of abbreviated new drug submissions (generic drugs) that did not meet service standards took, on average, 353 days (173 days longer than the 180-day standard).
 - Reviews of DIN-A submissions (primarily over-the-counter drugs) that did not meet service standards took, on average, 539 days (329 days longer than the 210-day standard).
 - Reviews of post-market manufacturing and safety-related labelling change submissions that did not meet service standards took, on average, 251 and 158 days, respectively (161 and 68 days, respectively, longer than the 90-day standard).

Exhibit 4.2 Health Canada is not meeting its own service standards for reviewing most drug submissions

Submission type	Description		Percentage that meet service standards (target 90%)	
		Service standard for first review decision*	2009	2010
New drugs				
New drug submission	Required for new drugs that have not been sold in Canada for a sufficient time and in sufficient quantity to establish their safety and effectiveness—includes clinical trial information and details on production, packaging, labelling, conditions for use, and side effects	300 calendar days	70%	70%
Supplemental new drug submission	Required if substantial changes are made to a drug previously approved as a new drug submission, including dosage form, drug strength, method of manufacture, and labelling; or the manufacturer wishes to expand the diseases or conditions the product is approved to treat	300 calendar days	92%	91%
Generic drugs				i
Abbreviated new drug submission	Required for new generic drugs; submissions must include evidence that the generic is equivalent to the existing patented drug (delivers the same amount of medicinal ingredient and at the same rate)	180 calendar days	36%	12%
Supplemental abbreviated new drug submission	Required if changes are made to a new generic product that was previously approved as an abbreviated new drug submission, including method of manufacture, labelling, recommended route of administration, or a new indication	180 calendar days	71%	5%
Over-the-counter drugs				
Drug identification number (DIN) applications	A DIN-A application is used most commonly for over-the- counter drugs that have established safety records but that require additional supporting data and a clinical review.	210 calendar days	19%	36%
	A DIN-F application is used most commonly for over-the- counter drugs that comply with existing drug labelling and that do not require additional supporting scientific data.	45 calendar days	93%	83%
Post-market (notifiable)	changes			L
Chemistry or manufacturing changes	Manufacturers must inform Health Canada of changes to a drug that could adversely affect its safety, purity, potency, or effectiveness.	90 calendar days	9%	14%
Labelling and product monograph changes	Manufacturers must inform Health Canada of changes to a drug that could adversely affect its safety, purity, potency, or effectiveness.	90 calendar days	57%	70%

Note: These service standards exclude the screening times to assess the completeness of a submission.

* A first decision can result in a request for additional information from the manufacturer, a rejection of the submission, or an approval.

Risk communication—The development and dissemination of information about potential or existing health risks, to enable patients and their health care professionals to make better informed decisions about their health.

Health Canada's four review bureaus—Drug review responsibilities are divided among four review bureaus based on the type of review required, the drug's therapeutic class, and whether the drug will be available by prescription or over the counter.

Three clinical review bureaus are responsible for assessing drugs that treat specific diseases, such as cancer or HIV. The fourth bureau reviews submissions for generic drugs and reviews the manufacturing and chemistry component of all drug submissions. The four review bureaus comprise eleven more specialized review units.

- 4.49 According to Health Canada, a number of factors can contribute to poor review performance. For example, drug reviewers are often required to perform duties other than reviewing submissions, such as
 - assessing the potential health risks posed by defective or illegal products; or
 - contributing to related **risk communications**, so the public is informed of potential safety risks.
- 4.50 We found that Health Canada has taken a number of steps to improve its review performance. Foremost among these was a new cost recovery framework, implemented in April 2011. The Department expects that the additional revenue, obtained by charging the pharmaceutical industry increased fees, will improve review times. The new user fees will be governed by the *User Fees Act*, which includes penalties (of up to 50 percent of the fees) for the Department if it does not meet its service standards. This means that the Department would receive less revenue from user fees, which could in turn reduce its resources for reviewing submissions.
- 4.51 We also found that the Department launched an initiative in June 2010 to develop a consistent approach to the use of foreign regulatory information in order to improve review efficiency. Health Canada's four review bureaus have each explored different approaches to reduce existing backlogs and to improve review performance, such as assessing workloads to determine the actual number of hours required to review drug submissions and the time spent on non-review activities. They expect this work will help streamline review processes and improve planning.
- 4.52 Canadians and health care professionals benefit from timely access to safe and effective drugs. It is important that Health Canada take the necessary time to properly evaluate a drug for safety and efficacy, but delays in approving new drug submissions mean that access to the potential benefits of these drugs is delayed. The untimely review of abbreviated (generic) new drug submissions may limit access to more affordable treatments. The delayed review of post-market change submissions, particularly those for labelling changes to address potential safety issues identified by the pharmaceutical industry or by the Department, means that new safety information may not be provided to Canadians as quickly as possible.
- **4.53** Recommendation. Health Canada should ensure that it meets service standards for the review of all drug submission types—by giving due consideration to the appropriate allocation of additional resources

from increased fees charged to industry, to the use of foreign regulatory information, and to streamlining its review processes.

The Department's response. Agreed. Revenues from recently updated user fees will allow the Department to meet its well-established and internationally recognized performance standards. The Department will closely monitor its performance. It will continue to seek process efficiencies, such as increasing the leverage of external scientific expertise and the use of foreign regulatory information. The Department will begin piloting an approach to enhance and formalize the use of foreign reviews through standard operating procedures and guidance for industry in the fall of 2011 and will complete an evaluation of the pilot by 31 March 2014.

Health Canada has not assessed whether its review bureaus interpret and apply review procedures and guidelines consistently

- 4.54 We examined whether Health Canada had established a quality assurance system for its review of drug submissions. In a strategic plan for these reviews—Therapeutic Products Directorate Strategic Plan, 2006–2009, The Way Forward—the Department acknowledged the importance of consistent, timely, and high-quality review decisions.
- **4.55** We found that the Department has the following key components of a quality assurance system:
 - standard operating procedures,
 - guidelines for drug reviewers,
 - review templates,
 - training programs, and
 - management review of individual files.
- 4.56 However, we also found that Health Canada has not assessed whether review procedures, guidelines, and templates were consistently interpreted and applied across the four different review bureaus responsible for conducting reviews of drug submissions. Such an assessment would allow the Department to identify inconsistencies between the different review bureaus that may affect the timeliness and quality of review decisions.
- **4.57 Recommendation.** Health Canada should regularly assess whether the procedures and guidelines, which were established to ensure timely, consistent, and high-quality review decisions, are interpreted and applied consistently by all four review bureaus.

The Department's response. Agreed. The Department will develop a system to regularly assess and ensure the use of procedures established to ensure timely, consistent, and high-quality review decisions by 31 December 2012. Implementation of the system, which will include assessment of compliance with procedures and consistency of interpretation across organization review units, and necessary corrective mechanisms to ensure consistent use, will be completed by 31 December 2013.

More information on Health Canada's reviews of drug submissions needs to be made available to Canadians

- 4.58 We examined several of Health Canada's commitments to increase the transparency of review decisions and the amount of information it makes available to Canadians about approved drugs. These commitments are consistent with government-wide directives to foster understandable and responsive regulation through inclusiveness, transparency, accountability, and public scrutiny. It is important that Canadians have access to information so they are able to make informed decisions about the drugs they use.
- 4.59 To determine whether Health Canada had fulfilled its commitments for increasing the transparency of review decisions, we examined the availability and the timeliness of the public disclosure of key documents to its website (product monograph, notice of decision, summary basis of decision) for all 34 new active substances approved in 2009 and 2010. We found that, while it had met its timelines for posting product monographs, the Department had not consistently met its timelines for posting notice of decision or summary basis of decision documents (Exhibit 4.3).
- 4.60 Health Canada occasionally attaches conditions to a drug's approval, asking the manufacturer to carry out additional post-market studies. We found that the Department does not disclose the timelines established for fulfilling these conditions, nor does it report on the progress made by manufacturers in fulfilling these conditions. We noted that the US Food and Drug Administration does provide updates on the status of post-market conditions.
- 4.61 Health Canada told us that, until recently, manufacturers were not asked to report regularly on their progress in fulfilling post-market conditions. Since June 2011, manufacturers have been asked to provide annual updates, but they are under no regulatory obligation to do so.
- **4.62** Health Canada is also not disclosing information on drugs that it rejects or on drugs that the manufacturer withdraws from the review

New active substance—A chemical not previously authorized for sale in Canada as a drug.

process. Health care providers have the discretion to prescribe a drug for conditions that the drug has not been authorized to treat. Therefore, it is important that they be informed when the Department rejects a marketed drug for a new use, so they understand the Department's concerns. We also noted that the European Medicines Agency, which is responsible for the scientific evaluation of medicines for use in the European Union, discloses information related to rejections and withdrawals of drug submissions.

Exhibit 4.3 The Department did not consistently meet its own timelines for posting review documents for drugs with new active substances

Document	Description	Posting timeline	Number reviewed	Number posted within the timeline
Product monograph	Describes the health claims, indications, and conditions for the safe and effective use of a drug. It also includes other important information, such as safety warnings, precautions, adverse reactions, and interactions with other drugs.	At the time of market notification	28*	28 met the timeline
Notice of decision	Outlines in a one-page summary the authorization received and general information related to the approved drug.	Within 6 weeks of drug approval	31**	20 met the timeline11 took an average of 3 weeks longer
Summary basis of decision	Outlines the scientific and benefit or risk considerations that factor into Health Canada's decision to approve a drug.	Within 20 weeks of drug approval	31**	 15 met the timeline 15 took an average of 12 weeks longer 1 was not yet posted

^{*} Five of the new drugs approved during the period subject to audit have not been marketed in Canada, and one of the new drugs was discontinued. Therefore, a product monograph was not required for these six drugs.

4.63 Recommendation. Health Canada should disclose information related to new drug approvals in a timely manner and improve the transparency of "approvals with conditions," rejections, and withdrawals of new drugs so that Canadians and health care professionals can access information about these drugs.

The Department's response. Agreed. The Department will improve the transparency of approvals with conditions, rejections, and withdrawals to the Canadian public. The Department will consult with stakeholders in fall 2011 about expanding its public communications on post-approval decisions for marketed health products to include information on approvals with conditions, rejections, and withdrawals, with a view to disclosing additional information by June 2012.

^{**} Three new drugs approved in the period subject to audit were not considered to be new active substances. Therefore, they were not eligible for a Notice of Decision or a Summary Basis of Decision document.

Health Canada has not determined what measures are necessary to manage conflict-of-interest risks for drug reviewers

4.64 In the federal government, "conflict of interest" refers to a conflict between the public service duties and private interests of public servants. In the 2010 Fall Report of the Auditor General, Chapter 4, Managing Conflict of Interest, we noted that

... conflicts of interest bring into question the integrity and fairness of decisions made by public servants. If not properly addressed, conflicts of interest can increase the level of distrust and cynicism toward government and, over time, impact the legitimacy and effectiveness of government actions.

- **4.65** The government's Values and Ethics Code for the Public Service requires that departments establish measures to manage conflicts of interest. To determine whether Health Canada had systems to manage conflict-of-interest risks to the drug submission review process, we examined its Code of Conduct and its conflict-of-interest guidelines, and interviewed key entity officials. The audit was not designed to find cases of officials being in a conflict of interest, and we did not find any such cases.
- 4.66 We found that Health Canada's code of conduct and conflict-of-interest guidelines are consistent with the government's Values and Ethics Code for the Public Service. However, in 2010, the Department had not complied with the code's requirement to issue an annual reminder to employees of their conflict-of-interest obligations and, at the time of our audit, the Department had not issued this reminder for 2011.
- 4.67 Compliance measures beyond those specified in the Values and Ethics Code for the Public Service are permitted if a department believes they are necessary to address its specific responsibilities. Officials responsible for reviewing drug submissions routinely handle commercially sensitive information that could be used for personal gain, and they are directly involved in making decisions that could have significant commercial benefits. However, we found that the Department has not determined what measures are necessary to address these risks.
- 4.68 In our 2010 Fall Report, Chapter 4, Managing Conflict of Interest, we noted that some government departments had developed conflict-of-interest requirements for specific work assignments. For example, Natural Resources Canada requires staff assigned to the management of contribution agreements to acknowledge in writing

that they understand what to do to avoid and disclose conflicts of interest for each agreement in which they are involved.

- **4.69** We also noted that the European Medicines Agency requires that its employees' declarations of interests be updated annually and that its drug reviewers' declarations be checked each time they are assigned to review a new drug submission.
- **4.70** Recommendation. Health Canada should assess the risks posed by conflicts of interest to the drug review process, determine what measures are necessary to manage these risks, and implement those measures.

The Department's response. Agreed. The Department requires disclosure of potential conflicts of interest at the initiation of employment, and employees are subject to the Values and Ethics Code for the Public Service. The Department will determine if there are any particular risks posed by potential conflicts of interest in the drug review process by 31 March 2012 and, if necessary, develop and implement additional measures by 30 September 2012.

Monitoring post-market safety

- 4.71 Health Canada monitors the safety of marketed drugs by collecting, analyzing, and assessing domestic adverse drug reaction reports that are submitted by the pharmaceutical industry, health professionals, and consumers. The Department also collects foreign adverse drug reaction reports that are submitted by the pharmaceutical industry. In addition, it reviews scientific literature, as well as actions taken by other regulators, to address safety concerns identified from these sources. The Department uses this information to determine whether further action is needed to protect the public, including
 - conducting full assessments of potential safety issues,
 - recommending that manufacturers revise product labels and working with manufacturers to implement these revisions, and
 - communicating new safety information to health care providers and the public.
- 4.72 We examined Health Canada's approach to monitoring the safety of drugs marketed in Canada. According to its post-market surveillance strategy, the Department is responsible for ensuring that the benefits of using a drug outweigh the risks. It fulfills this responsibility by gathering and assessing safety information, from a

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variety of sources, and by implementing measures necessary to reduce the safety risks associated with marketed drugs. To determine whether the Department uses a risk-based approach for monitoring marketed drugs, we examined its processes for obtaining, assessing, and acting on drug safety information.

Health Canada has recently taken additional steps to actively monitor drug safety

- 4.73 In 2010, Health Canada received about 30,000 domestic adverse drug reaction reports and about 330,000 foreign reports. The vast majority of these reports were submitted by the pharmaceutical industry, which is required to report adverse reactions to the Department. Adverse drug reaction reports are an important component of monitoring drug safety.
- 4.74 We found that Health Canada does not have mechanisms to receive these adverse reaction reports electronically, and it has not entered the foreign reports it receives each year in its post-market adverse drug reaction database. Adverse drug reactions captured in this database may help identify potential safety issues. Although the Department can consult foreign adverse drug reaction reports when necessary, it does not regularly analyze these reports or search them electronically to detect emerging safety issues. Canada's small population reduces the likelihood of serious, rare adverse drug reactions being identified in this country; therefore, the capacity to search and analyze foreign reports electronically would contribute to more comprehensive safety monitoring.
- **4.75** The Department expects to begin electronic reporting pilots in the 2011–12 fiscal year. When electronic reporting is fully implemented, the Department believes it will have the capacity to electronically capture and analyze the foreign reports it receives each year.
- 4.76 We found that Health Canada had recently implemented strategies to electronically search its domestic adverse drug reaction reports, to better detect adverse reactions for specific drugs, and to systematically monitor those adverse reactions that are rare, serious, and often linked to marketed drugs. A similar approach to monitoring adverse drug reaction data for vulnerable populations (for example, children) has yet to be implemented.
- 4.77 Due to the limitations of adverse drug reaction reports, the World Health Organization has encouraged regulators to incorporate active surveillance into their monitoring activities. We found that,

Risk management plan—A set of monitoring activities and interventions by the manufacturer designed to identify, characterize, prevent, or minimize risks relating to drugs and designed to assess the effectiveness of those interventions.

since 2009, Health Canada has taken several steps to increase active monitoring, including the following:

- establishing formal working groups to systematically consider potential safety issues that were identified by other regulators, reported in scientific journals, or identified by industry;
- implementing an inspection program to ensure that companies comply with regulatory requirements to report adverse drug reactions; and
- reviewing risk management plans voluntarily submitted by the pharmaceutical industry, as part of some drug submissions, which may identify potential safety issues and include manufacturers' commitments to actively monitor the drug.
- 4.78 The Department has acknowledged that it had not yet set up monitoring systems to identify adverse drug reactions in patients who are taking certain drugs or to detect adverse reactions in health care settings, such as emergency departments, where those suffering an adverse reaction may seek treatment. However, the Department has recently launched an initiative to identify more active surveillance activities and to determine their potential value.

Health Canada's assessment of, and response to, potential safety issues is not timely

- **4.79 Assessing safety issues.** Health Canada uses information obtained through its monitoring activities to assess whether there may be a safety issue with a specific drug. Depending on the results of its assessment, it may recommend changes to the drug's label, issue a risk communication to the public or health care professionals about the risks of using the drug, or do both.
- 4.80 In certain instances, Health Canada may also withdraw a drug's market approval. It is important to note that the Department has indicated that after it has approved a drug for sale, it has limited authority to require that manufacturers update drug labels or issue risk communications about new safety concerns. Overall, we found that the Department did not assess potential safety issues, detected through its monitoring activities, in a timely manner. Therefore, changes to drug labels and risk communications were also not timely.
- 4.81 In 2009 and 2010, Health Canada completed 99 assessments of potential safety issues, which were identified through its post-market monitoring activities. The Department had established draft risk-based timelines for these assessments. Of the 99 assessments, 54 resulted in recommendations about updating the labelling for specific drugs or

classes of drugs and issuing risk communications. Almost half of the assessments that resulted in recommendations were triggered by actions taken by other regulators (Exhibit 4.4).

Exhibit 4.4 The greatest number of Health Canada safety recommendations resulted from actions by foreign regulators

Source of safety assessment that resulted in recommendation	Number of recommendations
Actions of foreign regulators	25
Safety information from scientific literature	15
Adverse drug reaction reports, and previous Health Canada assessments of potential safety issues	9
Safety information provided by manufacturers	5
Total	54

4.82 We reviewed all 54 of these assessments (Exhibit 4.5). It is important that these assessments be completed in a timely manner, so if there are safety risks they can be confirmed and communicated to Canadians.

Exhibit 4.5 Health Canada does not consistently meet its targets for completing safety assessments

			Actual performance	
Priority rating	Performance target	Assessments reviewed Met		Not met
High—Potential safety issues that, if confirmed, will likely require an intervention. These include adverse drug reactions that were unknown, unlabelled, or insufficiently labelled.	80 working days	0	0	0
Medium—Potential safety issues that are not as serious or not as unexpected, but still require a comprehensive assessment. If confirmed, these safety issues are likely to require labelling changes.	130 working days	29	16	13
Low—Potential safety issues that are well known or labelled. These issues are not likely to affect the way a drug is used.	200 working	25	:8	7
Total		54	34	20

- 4.83 Of the 54 assessments we examined, 34 were completed within the established timelines. However, the Department's approach to measuring its performance does not consider the following:
 - amount of time a potential safety issue may wait before an assessment begins;
 - amount of time an assessment may be placed on hold;
 - amount of time needed to obtain additional information from external parties (for example, manufacturers or other regulators); and
 - total number of calendar days, instead of working days, taken to complete the assessment.
- 4.84 When these factors are considered, Health Canada took at least one year to complete 34 of its 54 assessments. In some cases, it took significantly longer. For example, 5 medium-priority assessments required more than two years to complete, and 1 of the 5 required more than three years to complete.
- 4.85 Although Health Canada did not conduct any high-priority safety assessments in 2009 and 2010, we noted that two drugs were voluntarily withdrawn by manufacturers from the Canadian market for safety reasons during that period. Both withdrawals occurred after new studies confirmed that the risks of using the drugs outweighed any benefits. One of these drugs was withdrawn by the manufacturer before the Department had completed an ongoing safety assessment, and the other was withdrawn without an assessment being conducted. In both cases, the Department publicly announced the withdrawals at approximately the same time as the US Food and Drug Administration.
- 4.86 Updating drug labels and communicating health risks. According to its post-market surveillance strategy, Health Canada is responsible for managing identified safety risks, which includes communicating health risks to health care professionals and the public, and working with manufacturers to update drug labels with the most recent safety information. Of the 54 safety assessments we examined, Health Canada had recommended 51 labelling updates and 24 risk communications. It is important that these recommendations are implemented so that health care providers and consumers have access to the most up-to-date safety information available.
- **4.87** We found that there is no systematic process to implement recommendations for labelling updates. This is important because officials responsible for making safety-related recommendations are not

the same officials responsible for working with the drug manufacturers to implement these recommendations. We found that the officials responsible for implementing recommendations often do not document whether they agree or disagree with recommended labelling updates or how they intend to implement the recommendations, including what the proposed timelines are for implementation.

- **4.88** Once the Department has decided to implement a recommendation to update a drug's label to include new safety information, its officials are responsible for starting the process, by notifying the manufacturer of the requested update. We found that the Department has not established timelines for issuing these notifications.
- 4.89 Health Canada needed to notify manufacturers about 38 of the 51 recommended label updates. It did not need to notify manufacturers about the other 13 because in some of those cases, the manufacturer had already updated the labelling, and, in others, the Department was already reviewing a manufacturer's submission to address the recommendation.
- 4.90 We found that for 12 of these 38 recommended updates, it took Health Canada between 3 and almost 20 months to issue notifications to manufacturers. We also found that the Department had not yet notified the manufacturer of another 6 recommended label updates, even though between 6 and 28 months had passed since the recommendations were first made. Officials told us that the Department may delay notifying manufacturers of requested label updates if it does not have the resources available to review all the submissions that will result from the request. For example, according to the Department, one label update that affects a class of drugs could generate well over 100 notifiable change submissions.
- 4.91 We also found that labelling recommendations are not directly communicated to the departmental officials who are responsible for working with the pharmaceutical industry to update labels for generic drugs. As a result, these officials may not be informed of key safety issues, and labels on generic drugs may not be updated in a timely manner. According to IMS Brogan, 57 percent of prescriptions dispensed by Canadian retail pharmacies in 2010 were for generic drugs. The case study on a label change for a drug to treat epilepsy shows the impact of not formally tracking safety recommendations—that is, how undefined processes and poor communications can result in inconsistent labelling between brand name and generic drugs.

Case study—Label change for a drug to treat epilepsy

In August 2009, Health Canada completed a safety assessment on a drug approved to treat epilepsy and migraine headaches, which was also used off-label to treat several psychiatric conditions and to promote weight loss. The completed assessment recommended that the drug's label be updated to reflect newly identified risks related to increased incidence of birth defects.

In September 2009, the Department sent a letter to the brand-name manufacturer of the drug requesting that the drug's label be updated to reflect this new safety information. In April 2010, the label for the brand name drug was revised.

According to Health Canada, generic drug manufacturers should update safety information so generic drug labels are consistent with those for brand-name drugs. The Department has a practice of alerting generic manufacturers when a brand-name drug revises its labelling to address new safety issues.

Health Canada officials responsible for working with the generic drug industry were not notified of the required labelling changes until February 2011—almost one year after the brand name drug changed its product monograph. Hence, the Department did not inform the 12 generic manufacturers with outdated product monographs of the need to update these documents until March 2011. The Department did not need to inform two other manufacturers of the drug, because they had already updated their product monographs. As of 31 May 2011, they remain the only generic drug manufacturers marketing this drug in Canada with updated product monographs.

- 4.92 Safety assessments may also recommend that risk communications be issued to inform the public of new drug safety information. We found that of the 24 recommended risk communications that we examined, 11 were not issued by Health Canada until six months after the assessment had been completed. In three cases, we found that the Department took more than a year to issue a recommended risk communication.
- 4.93 According to Health Canada, in less urgent cases, the Department does not issue a risk communication until a drug's label has been updated to reflect the most recent safety information.
- 4.94 As noted earlier, the Department does not complete its safety assessments, or notify manufacturers of requested label updates, in a timely manner, and it does not consistently meet its service standards for the review of notifiable change submissions (Exhibit 4.2). As a result, a significant amount of time can pass before recommended risk communications are issued to Canadians.
- 4.95 Overall, we found that for 11 of the 24 recommended risk communications that we examined, it took the Department more than two years to assess the potential safety issue, update the drug's label (where necessary), and issue the risk communication.

Case study—Delayed risk communication for two commonly used drugs

In 2006, the US Food and Drug Administration released a public risk communication stating that the therapeutic effectiveness of daily low-dose acetylsalicylic acid (ASA) therapy was potentially reduced when ibuprofen was taken at the same time. Health Canada started to assess this potential safety issue in January 2006 and finished in September 2009. It recommended that labels for products containing acetylsalicylic acid and ibuprofen be updated and that a risk communication be issued to inform Canadians of this new safety information. As of May 2011, not all labels for the several hundred affected products had been updated, and Health Canada had not issued the recommended risk communication.

4.96 Recommendation. Health Canada should improve the timeliness of safety assessments and the implementation of related recommendations to update labels and to issue risk communications, so Canadians and health care professionals can be informed of new drug safety information in a timely manner.

The Department's response. Agreed. The Department will improve the timeliness of safety assessments by fully implementing and respecting related performance standards by December 2013. This involves reviewing baselines for completing safety reviews.

4.97 Recommendation. Health Canada should establish a systematic process to manage safety assessment recommendations for marketed drugs, to ensure that recommendations are dealt with appropriately and in a timely manner.

The Department's response. Agreed. The Department will establish a systematic process to implement safety assessment recommendations for marketed drugs. The Department has already begun developing a standard operating procedure in this regard. The standard operating procedure will include new formalized tracking systems (currently under development) and necessary implementation procedures following a safety assessment recommendation. This will be in place by 31 March 2013.

4.98 Assessing the effectiveness of risk communications. In addition to communicating safety risks to Canadians in a timely manner, it is important for Health Canada to know whether its risk communications are effective and have an impact on targeted audiences. In Planning for Our Future: Federal Regulatory Post-Market Surveillance Strategy 2007–2012, the Department includes a commitment to evaluate the effectiveness of its risk management actions.

4.99 We found that Health Canada has not assessed the effectiveness of risk communications but has begun to examine this issue. For example, the Department commissioned a study of how health care professionals use its risk communications: specifically, the impact of these communications on prescribing patterns in Canada. Officials told us that assessing the impact of risk communications on behaviour is also challenging for foreign regulators, because there is no widely accepted approach to measuring the effectiveness of risk communications.

Enforcing compliance with the regulations

- 4.100 Health Canada's compliance and enforcement activities are conducted by inspectors in its regional offices. The Department maintains a national inspection program that examines the operations of various drug establishments, such as manufacturers, wholesalers, and distributors—to verify that the pharmaceutical industry is complying with the internationally accepted Good Manufacturing Practices, which are set out in the *Food and Drug Regulations*.
- **4.101** Serious deficiencies identified during an inspection can result in a request for a product recall or the suspension of an establishment licence. Health Canada also follows up on reported complaints or concerns, such as those related to the illegal sale of pharmaceutical drugs or the quality or safety of those available for sale. The Department also monitors the industry's implementation of product recalls.

Actions have been taken to make inspections of drug establishments more risk-based

- 4.102 Health Canada inspects Canadian drug establishments to verify that they comply with the good manufacturing practices required by the Food and Drug Regulations, which reduces the likelihood that Canadians will be exposed to substandard drugs. The Department's draft Compliance and Enforcement Risk Evaluation Guide: An Approach to Decision Making specifies that compliance and enforcement activities associated with regulated products or activities need to be appropriate and proportional to the risks.
- **4.103** We found that the Department has established risk-based inspection cycles for drug establishments based on the nature of their activities. For example, drug manufacturers were inspected every two years, whereas lower-risk establishments, such as distributors, were inspected every three years.
- **4.104** In June 2010, Health Canada completed a review of its drug establishment inspection program and recommended that the program

be more risk-based. As a first step, in April 2011, the Department eliminated renewal inspections that are normally conducted when annual establishment licences expire. It expected that this change would enable inspectors to focus on high-risk establishments, as opposed to those requiring an inspection as part of the licence renewal process. Other recommendations arising from this review were also being implemented.

4.105 Foreign manufacturers. According to Health Canada, approximately 80 percent of health products used by Canadians are manufactured in other countries. The Department established mutual recognition agreements with 26 international partners to ensure that drugs manufactured in these jurisdictions and imported into Canada comply with the Good Manufacturing Practices required by the *Food and Drug Regulations*.

Complaints about marketed drugs are not prioritized consistently

4.106 We examined whether Health Canada used a risk-based approach to follow up on complaints about drugs, and whether it verified compliance with the *Food and Drug Regulations*. The Department's draft Compliance and Enforcement Risk Evaluation Guide: An Approach to Decision Making specifies that compliance and enforcement activities associated with a regulated product or activity be appropriate and proportional to the risk. Verifying the regulatory compliance of marketed drugs is critical to ensuring that Canadians are not exposed to unsafe drugs.

4.107 To determine whether Health Canada used a risk-based approach, we

- reviewed its performance reports and standard operating procedures, for its compliance verification activities;
- interviewed its key officials in Ottawa and in its three largest regional operational centres; and
- reviewed a representative sample of 50 files related to drugspecific complaints that were also closed in 2009 or 2010.

4.108 In 2009 and 2010, the Department received almost 800 complaints concerning specific drugs from consumers, health care professionals, the pharmaceutical industry, and other stakeholders. Health Canada had established risk-based standard operating procedures for prioritizing reported cases of non-compliance to ensure that compliance and enforcement actions are initiated within specified timelines. However, we found that these procedures were not

implemented consistently. In 27 of the 50 complaint files we reviewed, we found that the Department had not prioritized these complaints using its standard operating procedures. Therefore, the Department could not demonstrate that compliance and enforcement actions were initiated in a timely manner. For 12 of the 23 complaints that were prioritized in accordance with procedures, we found that the Department had initiated compliance and enforcement actions within the established timelines.

4.109 Recommendation. Health Canada should consistently apply its risk-based standard operating procedures, so the priority of the drug complaints it receives is properly documented and addressed in a timely manner.

The Department's response. Agreed. The Department strives to ensure that complaints received are addressed in a timely manner and are properly documented. The Department will review its processes to ensure better documentation, conduct training sessions, and implement more robust performance monitoring by 31 March 2013.

Conclusion

4.110 We conclude that Health Canada has fulfilled its responsibilities for the timely review of clinical trial applications and amendments. However, it has not adequately fulfilled its key responsibilities for verifying the regulatory compliance of authorized trials. Although Health Canada has a risk-based clinical trial inspection strategy, it does not have all the information it needs to make comparative risk-based decisions about which sites to inspect, and it does not regularly report on its clinical trial inspection activities. The Department had also not met its clinical trial inspection target in 2009 or 2010. Furthermore, the Department does not document its approach to monitoring adverse drug reactions in clinical trials to ensure that it focuses on the trials that posed the greatest risk. It did not fulfill long-standing commitments to increase the transparency of authorized clinical trials.

4.111 Health Canada did not review most drug submissions within its established service standards and did not assess whether its four review bureaus consistently interpret and apply procedures designed to support timely, consistent, and high-quality reviews of drug submissions. The Department increased the amount of information publicly available on approved drugs and on its rationale for approving these drugs. However, this information could be timelier. The Department does not disclose information on drug submissions that were rejected or withdrawn.

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- 4.112 Health Canada's conflict-of-interest guidelines are consistent with the government's Values and Ethics Code for the Public Service. However, in 2010, the Department had not complied with the code's requirement to issue an annual reminder to employees of their conflict-of-interest obligations. At the time of our audit, the Department had not yet issued this reminder for 2011, nor had it determined the necessary measures to address the conflict-of-interest risks specific to its review activities. Some federal government departments and a major regulator of pharmaceuticals have developed additional measures to manage conflicts of interest for specific activities.
- **4.113** Health Canada has not adequately fulfilled its key responsibilities for monitoring the safety of marketed drugs. It recently took steps to actively monitor drug safety, and it is developing the capacity to process and analyze foreign adverse drug reaction reports that it receives from the pharmaceutical industry. The Department developed a risk-based approach to assessing the safety issues it identified through its monitoring activities, and it has established timelines for this work. However, it does not complete these assessments or communicate safety concerns in a timely manner, and it has not established systematic processes for implementing the recommendations that result from these assessments.
- **4.114** Health Canada has fulfilled its key responsibilities for verifying the regulatory compliance of industry. It takes a risk-based approach to inspecting drug establishments and is working to strengthen this approach. However, although the Department developed a risk-based approach for following up on complaints about specific drugs, it does not apply it consistently.
- **4.115** In summary, we examined key Health Canada responsibilities involving timeliness, consistency, transparency, conflict of interest, and risk-based post-market activities. We found that the Department has not adequately fulfilled most of these key responsibilities related to clinical trials, submission reviews, and post-market activities for pharmaceutical drugs.

About the Audit

All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by The Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

Objectives

The overall audit objective was to determine whether Health Canada fulfilled its key responsibilities related to clinical trials, submission reviews, and post-market activities for pharmaceutical drugs.

The audit sub-objectives were to determine whether the Department fulfilled its key responsibilities for

- conducting timely clinical trial application reviews;
- supporting the transparency of authorized clinical trials, and verifying their regulatory compliance;
- conducting timely and consistent submission reviews;
- supporting the transparency of review outcomes;
- implementing systems to manage conflicts of interest;
- · monitoring the safety of marketed pharmaceuticals;
- · communicating safety concerns in a timely manner; and
- · verifying the regulatory compliance of industry.

Scope and approach

Our audit focused on the three Health Canada directorates that are involved in the regulation of pharmaceuticals. We examined the timeliness of reviews for clinical trial applications and for drug submissions, received from the pharmaceutical industry, for market authorization and post-market changes. Where necessary, we conducted gap analyses to assess the completeness of the data used by the Department to measure its review performance. We also verified the accuracy of the Department's data by conducting a file review of a representative sample of clinical trial applications and drug submissions.

We also examined whether the Department had established the necessary quality assurance systems to support consistency among its review activities and what efforts it had made to ensure the transparency of clinical trials by disclosing information about those that were in progress, abandoned, or completed. We also reviewed various departmental initiatives to increase the transparency of its drug submission reviews.

We examined the Department's safety monitoring activities for drugs being tested in clinical trials and for those already marketed, to determine whether the Department completed its assessments and ensured that safety-related recommendations, such as labelling updates and risk communications, were implemented in a timely manner.

We also examined compliance and enforcement activities to determine whether the Department had employed a risk-based approach to its inspection of clinical trial sites and pharmaceutical establishments and to its follow-up of product-specific complaints or concerns it had received from various stakeholders. As part of this work, we examined a representative sample of complaints. The sample size was sufficient to conclude on the sampled population with a margin of error of ± 10 percent 18 times out of 20.

We interviewed key Health Canada officials involved with regulation of pharmaceuticals at headquarters and in the larger regional offices and met with representatives from the pharmaceutical industry and the health care field. We reviewed documentation, including regulations, strategic and operational plans, program reviews, and reports filed by the Department's inspectors in the field.

We did not examine the following:

- regulation of biologics (products derived from living sources, such as blood and vaccines), radiopharmaceuticals (radioactive products used to diagnose illness), or disinfectants;
- completed reviews of drug submissions to determine whether drugs approved by the Department were safe or reviewed in a consistent manner;
- regulation of direct-to-consumer advertising or efforts at the border to prevent the importation of prescription or counterfeit pharmaceutical products; and
- the Special Access Program or Patented Medicines Prices Review Board.

Criteria

we used the following criteria:			
Criteria	Sources		
Health Canada reviews clinical trial applications in a timely fashion.	Guidance for Industry: Management of Drug Submissions, Health Canada		
	Food and Drug Regulations		
for verifying their regulatory compli	ance, we used the following criteria:		
Criteria	Sources		
Criteria The Department publicly discloses information related to clinical trials that are in progress, abandoned, or completed.	Sources • Blueprint for Renewal II: Modernizing Canada's Regulatory System for Health Products and Food, Health Canada		
The Department publicly discloses information related to clinical	Blueprint for Renewal II: Modernizing Canada's Regulatory		

The Department uses a risk-based approach to inspect clinical trial sites and to monitor adverse drug reactions in order to verify compliance with the *Food and Drug Regulations*.

- Framework for the Management of Risk, Treasury Board
- Decision-Making Framework for Identifying, Assessing and Managing Health Risks, Health Canada
- Health Product and Food Branch's Compliance and Enforcement Risk Evaluation Guide: An Approach to Decision-Making, Health Canada
- Food and Drug Regulations

To determine whether Health Canada fulfilled its key responsibilities for conducting timely and consistent submission reviews, for supporting the transparency of review outcomes and for implementing systems to manage conflicts of interest, we used the following criteria:

Criteria	Sources
The Department reviews pharmaceutical submissions in a timely manner.	User Fees Act
	Guidance for Industry: Management of Drug Submissions, Health Canada
The Department establishes quality assurance systems to support the consistent review of pharmaceutical submissions	Health Products and Food Branch Strategic Plan, Health Canada, 2007–2012
	Therapeutic Products Directorate Strategic Plan 2006–2009, Health Canada
	• ISO9001:2008
The Department publicly discloses information related to its review of pharmaceutical submissions that have been approved, rejected, or withdrawn	Cabinet Directive on Streamlining, Our Commitment to Canadians
	Health Products and Food Branch Strategic Plan, Health Canada, 2007–2012
The Department implements systems to manage risks to the review process arising from real, apparent, or potential conflicts of interest	Values and Ethics Code for the Public Service, Treasury Board
	Health Products and Food Branch Strategic Plan, Health Canada, 2007–2012

To determine whether Health Canada fulfilled its key responsibilities for monitoring the safety of marketed pharmaceuticals, for communicating safety concerns in a timely manner, and for verifying the regulatory compliance of the pharmaceutical industry, we used the following criteria:

Criteria	Sources
The Department uses a risk-based approach to monitor the safety of pharmaceuticals authorized for use in Canada	Federal Regulatory Post-Market Surveillance Strategy, Health Canada
	Therapeutic Access Strategy, Health Canada
The Department uses a risk-based approach to enforce industry's compliance with the sections of the <i>Food and Drug Regulations</i> pertaining to pharmaceuticals	Framework for the Management of Risk, Treasury Board
	Decision-Making Framework for Identifying, Assessing and Managing Health Risks, Health Canada
	Health Product and Food Branch's Compliance and Enforcement Risk Evaluation Guide: An Approach to Decision- Making, Health Canada
	Food and Drug Regulations
The Department communicates safety risks to health care professionals and the public in a timely manner and assessed the effectiveness of its communications	Federal Regulatory Post-Market Surveillance Strategy, Health Canada
	Description of Current Risk Communication Documents for Marketed Health Products for Human Use, Health Canada

Management reviewed and accepted the suitability of the criteria used in the audit.

Period covered by the audit

The period under audit was 1 January 2009 to 31 December 2010. Audit work for this chapter was substantially completed on 31 May 2011.

Audit team

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For information, please contact Communications at 613-995-3708 or 1-888-761-5953 (toll-free).

Appendix List of recommendations

The following is a list of recommendations found in Chapter 4. The number in front of the recommendation indicates the paragraph where it appears in the chapter. The numbers in parentheses indicate the paragraphs where the topic is discussed.

Recommendation	Response
Regulating clinical trials	
4.35 Health Canada should strengthen its risk-based approach for monitoring and assessing clinical trial adverse drug reaction reports and for inspecting clinical trial sites, so potential safety issues are mitigated. (4.16–4.34)	Agreed. The Department is strengthening its risk-based approach to monitor and assess clinical trial adverse drug reaction reports and clinical trial inspections. A detailed standard operating procedure and strategy guide has been developed to prioritize the review of individual adverse drug reaction reports. This approach was implemented on 4 July 2011. The Department expects to have completed a review of the existing risk-based process for selecting clinical trial inspection sites by fall 2011. This review will be used to assess the effectiveness of the existing process and to inform the development, documentation, and implementation of an enhanced process.
4.36 Health Canada should establish timelines for officially notifying clinical trial sites of non-compliant ratings and for reviewing proposed corrective measures to verify compliance with the Food and Drug Regulations. (4.16–4.34)	Agreed. The Department is currently reviewing and revising its existing standard operating procedure for conducting clinical trial inspections. This revised standard operating procedure will emphasize establishing timelines for key steps in the inspection process, including notification of non-compliant ratings and the review of proposed corrective measures. This work will be completed by 31 March 2013.
4.41 Health Canada should fulfill long-standing commitments to enhance public access to information on authorized clinical trials, including the results of its clinical trial inspections. (4.37–4.40)	Agreed. The Department will develop policies on enhancing public access to information on authorized clinical trials that respect privacy rights and legislation. Work began in 2011 and will be completed by 31 March 2013. The Department commits to publishing periodic reports regarding clinical trial inspections, to provide stakeholders and the public with a summary view of its inspection findings by 31 March 2012.

Recommendation

Response

Reviewing drug submissions

- 4.53 Health Canada should ensure that it meets service standards for the review of all drug submission types—by giving due consideration to the appropriate allocation of additional resources from increased fees charged to industry, to the use of foreign regulatory information, and to streamlining its review processes. (4.45–4.52)
- 4.57 Health Canada should regularly assess whether the procedures and guidelines, which were established to ensure timely, consistent, and high-quality review decisions, are interpreted and applied consistently by all four review bureaus. (4.54–4.56)
- 4.63 Health Canada should disclose information related to new drug approvals in a timely manner and improve the transparency of "approvals with conditions," rejections, and withdrawals of new drugs so that Canadians and health care professionals can access information about these drugs. (4.58–4.62)
- 4.70 Health Canada should assess the risks posed by conflicts of interest to the drug review process, determine what measures are necessary to manage these risks, and implement those measures. (4.64–4.69)

Agreed. Revenues from recently updated user fees will allow the Department to meet its well-established and internationally recognized performance standards. The Department will closely monitor its performance. It will continue to seek process efficiencies, such as increasing the leverage of external scientific expertise and the use of foreign regulatory information. The Department will begin piloting an approach to enhance and formalize the use of foreign reviews through standard operating procedures and guidance for industry in the fall of 2011 and will complete an evaluation of the pilot by 31 March 2014.

Agreed. The Department will develop a system to regularly assess and ensure the use of procedures established to ensure timely, consistent, and high-quality review decisions by 31 December 2012. Implementation of the system, which will include assessment of compliance with procedures and consistency of interpretation across organization review units, and necessary corrective mechanisms to ensure consistent use, will be completed by 31 December 2013.

Agreed. The Department will improve the transparency of approvals with conditions, rejections, and withdrawals to the Canadian public. The Department will consult with stakeholders in fall 2011 about expanding its public communications on post-approval decisions for marketed health products to include information on approvals with conditions, rejections, and withdrawals, with a view to disclosing additional information by June 2012.

Agreed. The Department requires disclosure of potential conflicts of interest at the initiation of employment, and employees are subject to the Values and Ethics Code for the Public Service. The Department will determine if there are any particular risks posed by potential conflicts of interest in the drug review process by 31 March 2012 and, if necessary, develop and implement additional measures by 30 September 2012.

Response Recommendation Monitoring post-market safety Agreed. The Department will improve the timeliness of safety Health Canada should improve the timeliness of safety assessments and assessments by fully implementing and respecting related performance standards by December 2013. This involves the implementation of related reviewing baselines for completing safety reviews. recommendations to update labels and to issue risk communications, so Canadians and health care professionals can be informed of new drug safety information in a timely manner. (4.73 - 4.95)Agreed. The Department will establish a systematic process to 4.97 Health Canada should establish a implement safety assessment recommendations for marketed systematic process to manage safety drugs. The Department has already begun developing a standard assessment recommendations for marketed drugs, to ensure that operating procedure in this regard. The standard operating recommendations are dealt with procedure will include new formalized tracking systems appropriately and in a timely manner. (currently under development) and necessary implementation procedures following a safety assessment recommendation. This (4.79 - 4.95)will be in place by 31 March 2013.

Enforcing compliance with the regulations

4.109 Health Canada should consistently apply its risk-based standard operating procedures, so the priority of the drug complaints it receives is properly documented and addressed in a timely manner. **(4.100–4.108)**

Agreed. The Department strives to ensure that complaints received are addressed in a timely manner and are properly documented. The Department will review its processes to ensure better documentation, conduct training sessions, and implement more robust performance monitoring by 31 March 2013.

Report of the Auditor General of Canada to the House of Commons—Fall 2011

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The Fall 2011 Report of the Auditor General of Canada comprises Matters of Special Importance, Main Points—Chapters 1 to 5, Appendices, and five chapters. The main table of contents for the Report is found at the end of this publication.

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Chapter

5

Maintaining and Repairing Military Equipment—National Defence

Performance audit reports

This report presents the results of a performance audit conducted by the Office of the Auditor General of Canada under the authority of the Auditor General Act.

A performance audit is an independent, objective, and systematic assessment of how well government is managing its activities, responsibilities, and resources. Audit topics are selected based on their significance. While the Office may comment on policy implementation in a performance audit, it does not comment on the merits of a policy.

Performance audits are planned, performed, and reported in accordance with professional auditing standards and Office policies. They are conducted by qualified auditors who

- establish audit objectives and criteria for the assessment of performance;
- gather the evidence necessary to assess performance against the criteria;
- report both positive and negative findings;
- · conclude against the established audit objectives; and
- make recommendations for improvement when there are significant differences between criteria and assessed performance.

Performance audits contribute to a public service that is ethical and effective and a government that is accountable to Parliament and Canadians.

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Maintaining and Repairing Military Equipment—National Defence

Main Points

What we examined

National Defence and the Canadian Forces own, operate, and are responsible for maintaining and repairing military aircraft, ships, and land vehicles costing more than \$30 billion. In 2009-10, National Defence spent more than \$2 billion to maintain and repair its military equipment. This included expenses for routine inspections, preventive maintenance, corrective repairs, spare parts supply, periodic repair and overhaul, engineering changes, and other related tasks.

Thousands of personnel are engaged in maintenance and repair activities, which include everything from turning wrenches on bases or while deployed on missions to engineering, logistics and spare parts management, training, contracting, and administrative support.

We examined how National Defence allocates and manages financial resources for the maintenance and repair of its military equipment. We also examined its approaches to contracting for maintenance and repair services.

Audit work for this chapter was substantially completed on 30 April 2011.

Why it's important

To undertake training and to meet assigned missions safely and successfully, military equipment must be kept in good working condition and be ready for action on short notice. How National Defence allocates the funds available—and the reliability of the information it uses to support short- and long-term decisions—is critical to the ability and readiness of the Canadian Forces to meet their assigned missions.

Military spending on maintenance and repair also makes a significant contribution to the Canadian economy every year. Many Canadian companies depend on it for a portion of their business. According to the 2008 Canada First Defence Strategy, the government plans to spend \$60 billion on new military equipment over 20 years and \$140 billion for spare parts, maintenance, and training.

Over the last decade, National Defence has made sweeping changes in its approach to contracting for maintenance and repair of both existing and new equipment. The changes transfer much of the responsibility to the private sector, with significant implications for National Defence and Canada's defence industry. The new contracting approach for existing equipment was intended to reduce the Department's contract management activities and costs by bundling hundreds of short-term maintenance contracts into a few longer-term contracts. The approach for new equipment goes even further, awarding both the acquisition and the long-term maintenance and repair contracts to the original equipment manufacturer or supplier. The Department has identified significant risks in this approach, including limited flexibility if requirements change over the life of the equipment, dwindling maintenance and repair skills and expertise in the Canadian Forces, and total dependence on one supplier for each fleet.

What we found

- Overall, National Defence has planned and managed the maintenance and repair of military equipment to meet operational priorities in the short term. The annual process of allocating available funds provides an effective forum to discuss priorities, with wide participation of those responsible for maintaining and repairing military equipment and those who need it for operations and training.
- National Defence's ability to meet training and operational requirements over the long term is at risk due to weaknesses in implementation and oversight of its contracting approaches for maintenance and repair, deficient management information systems, and the lack of sufficient cost and performance information.
- The Department has not taken the actions or provided the central resources and oversight required to support the implementation of its new contracting approaches successfully. The lack of concerted action and follow-through on the new contracting approach for existing military equipment has resulted in slower and more limited implementation than planned. As a consequence, National Defence has lost opportunities to derive the potential benefits of improved performance, improved accountability, and reduced costs. In addition, National Defence is not adequately monitoring and mitigating the significant risks created by its approach for new equipment.
- There are long-standing deficiencies in information management systems used to support decision-making for maintenance and repair activities, first raised by us in a 2001 audit. As a result, National Defence lacks complete, reliable, and integrated

information on the total actual costs of maintenance and repair, because some of the costs—salaries and infrastructure, for example—are not captured in its asset management information systems. The absence of this information impedes its ability to make informed decisions about the life-cycle management of its fleets or to determine whether it is putting enough funds each year into maintenance and repair. In 2001, National Defence expected to fully implement an integrated asset management system by 2004. The Department now expects a new system to be introduced on all Canadian Forces bases by mid-2012. Fully implementing this new system will likely take many years.

• There is a significant gap between the demand for maintenance and repair services and the funds made available. In addition, National Defence has indicated it is likely that its long-term investment plan for new equipment has allocated insufficient funds for equipment life-cycle costs. Although National Defence knows that postponing maintenance and repair tasks creates future risks—such as reduced availability of equipment, more laborious and expensive repairs, and reduced life expectancy of military equipment—the Department does not regularly monitor these impacts. Consequently, it does not know the specific long-term impacts of the funding gap on operations and training activities.

The Department has responded. The Department agrees with all of our recommendations. Its detailed responses follow the recommendations throughout the chapter.



Introduction

- 5.1 The Canada First Defence Strategy, released by the government in 2008, defines six core missions that the Canadian Forces must be prepared to undertake in Canada or abroad. Based on these missions, National Defence determines the capabilities that it needs to develop and sustain. To a large extent, sustaining these capabilities depends on military equipment being kept in good working condition and at a certain level of readiness. Effectively planning, supporting, and executing maintenance and repair activities for military equipment is therefore crucial to the Canadian Forces' ability to meet their core missions.
- 5.2 National Defence and the Canadian Forces own, operate, and are responsible for maintaining and repairing military equipment costing more than \$30 billion that is used for domestic and international operations and training. This military equipment includes 4 submarines, more than 30 large ships, over 350 aircraft, and about 9,000 military land vehicles. Maintaining and repairing all this equipment involves thousands of civilian and military personnel and many private sector firms in a diverse and often complex set of activities.
- 5.3 Military spending on maintenance and repair makes a significant contribution to the Canadian economy every year, and many Canadian companies depend on it for a portion of their business. If current trends continue, this contribution could increase in the future as more and more responsibility for providing maintenance and repair services is transferred to private sector firms in Canada and abroad. As announced in the 2008 Canada First Defence Strategy, the government plans to spend \$60 billion on new military equipment and \$140 billion on spare parts, maintenance, and training over 20 years.

Maintenance and repair activities, responsibilities, and budgets

- 5.4 At National Defence, maintenance is a preventive, scheduled activity that is intended to reduce the probability of equipment failure and extend the life of the asset. Repair is an activity that restores an item to serviceable condition by correcting faults or replacing unserviceable pieces with new, overhauled, rebuilt, or reconditioned components. Repairs are unpredictable and are thus more difficult to plan for and forecast than maintenance activities.
- 5.5 In the 2009–10 fiscal year, National Defence estimated that it spent just over \$2 billion to maintain and repair its military equipment. This included expenses for routine inspections, preventive

Military equipment—In this report, military equipment refers to ships, submarines, airplanes, helicopters, and land vehicles (armoured or not, wheeled or tracked) used by the Canadian Forces for training and operations. This equipment is also sometimes referred to as weapon systems. Each equipment or weapon system is made up of a number of subsystems (engines, radars, guns, radios, etc.), which consist of different parts. Military equipment is managed as a fleet when there are many ships, aircraft, or vehicles of the same model.

Readiness—A measure of the ability of a Canadian Forces unit to undertake an approved task. Readiness includes several aspects, including personnel, training, and equipment. National Defence establishes readiness standards or targets for most of its military equipment. This chapter focuses on equipment.

maintenance, corrective repairs, spare parts supply, periodic repair and overhaul, retrofits, engineering changes, preparation for special operations, and other related tasks. This amount did not include the salaries of personnel or the costs of infrastructure used to maintain and repair military equipment. The full spending on maintenance and repair activities is thus greater than \$2 billion.

- 5.6 The useful life of military equipment can sometimes extend more than 40 years from initial acquisition to final disposal. Maintenance and repair activities are categorized by National Defence into four different lines of work, based on their level of complexity and the time required to complete them. These activities can be performed by Canadian Forces technicians or by private sector firms:
 - Simple and short-term preventive maintenance and minor repair activities (first- and second-line) are carried out relatively frequently by civilians and military personnel on bases across the country or in the field. These tasks are typically completed within 24 hours.
 - Lengthier and more complex inspection, major repair, or complete equipment overhaul activities (third- and fourth-line) are centrally managed by the Assistant Deputy Minister (ADM) for Materiel, and are executed by the Department or by the private sector in specialized facilities. These tasks can take days, weeks, or months to complete.
- 5.7 These maintenance and repair activities are supported by equipment program management divisions that report to the ADM for Materiel. These divisions are responsible for the life-cycle management of aircraft, ships, and land vehicles; they identify maintenance and repair needs for each fleet, provide engineering and technical support, manage upgrade programs, and ensure that sufficient stocks of spare parts are purchased and made available to maintenance and repair technicians on a timely basis. Considerable variations exist in the specific ways that the Army, Air Force, and Navy carry out maintenance and repair for their equipment.

Findings from previous audit

5.8 We reported on National Defence's maintenance and repair activities in our 2001 chapter National Defence—In-Service Equipment. At the time, we observed that, in general, the information the Department needed to manage its maintenance and repair activities was often unavailable, incomplete, inadequate, or inaccurate. We also noted that budget restrictions, shortages of qualified

maintenance personnel, problems with spare parts supply, and aging equipment were having detrimental impacts on the Canadian Forces' ability to meet equipment readiness standards. Some training exercises and deployments had been affected by the unavailability of military equipment.

Changing approaches to maintenance and repair

- Since our previous audit, National Defence has faced a number of circumstances that have changed the context in which maintenance and repair activities take place.
 - Increased pace of operations. Canadian Forces have been deployed in Afghanistan since 2002, resulting in an increased pace of operations in the Army and the Air Force. This effort has accelerated the usage rates for various land vehicles and aircraft, increasing the need for maintenance and repair. In addition, deployment of qualified maintenance technicians to areas of operation abroad has meant that Army and Air Force units in Canada have had fewer technicians available to carry out maintenance and repair work.
 - Human resources challenges. For many years, the Department has faced shortages of skilled employees in some maintenance and repair trades. In addition, cuts made in the 1990s to National Defence human resources have resulted in fewer employees who are responsible for planning, managing, and contracting maintenance and repair activities. The looming retirement of baby boomers and ongoing competition with the private sector for qualified personnel are further challenges in this area.
 - Increasing cost. As they age, the cost of maintaining, upgrading, and repairing existing military fleets increases. In addition, modern replacements for old fleets usually carry more technologically advanced systems that cost more to maintain than the ones they are replacing. Total maintenance and repair costs over the complete life cycle of military equipment are often two or three times greater than the equipment acquisition cost.
- 5.10 In response to these and other challenges, over the past decade National Defence has explored new ways of meeting its maintenance and repair needs. In 2002, National Defence introduced the Optimized Weapon System Management (OWSM) program for existing military equipment and, in 2008, the In-Service Support Contracting Framework (ISSCF) for new equipment acquisitions. Consistent with practices in other countries, National Defence is increasing its use of

long-term, performance-based contracts with original equipment suppliers and/or specialized private sector firms. These new contracting approaches have meant sweeping changes for National Defence and its personnel, for federal departments (such as Public Works and Government Services Canada), and for the Canadian defence industry.

Focus of the audit

- **5.11** This audit examined whether National Defence planned and managed the maintenance and repair of its military aircraft, ships, and land vehicles to meet its operational and training requirements. More specifically, we examined whether the Department had
 - appropriately allocated and monitored financial resources for the maintenance and repair of its military equipment to meet training and operational requirements; and
 - appropriately established and implemented maintenance and repair contracting approaches for its military aircraft, ships, and land vehicles.
- 5.12 Our examination of the management of the various maintenance and repair funds covered the planning cycles for the 2009–10 and 2010–11 fiscal years. Our examination of contracting approaches covered the decade that has elapsed since our 2001 audit, because work on many of the long-term maintenance contracts that we looked at started in the early 2000s and is ongoing today.
- **5.13** More details about the audit objectives, scope, approach, and criteria are in **About the Audit** at the end of this chapter.

Observations and Recommendations

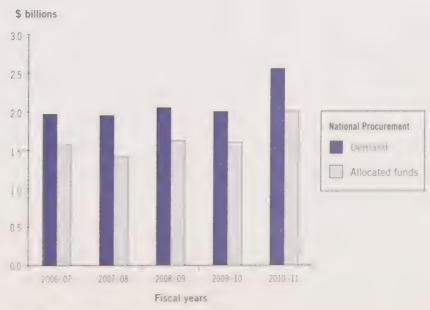
Allocation and monitoring of financial resources

- 5.14 The ultimate purpose of maintenance and repair activities is to ensure that military equipment meets operational requirements in a cost-effective manner over its intended useful life. If adequate maintenance cannot be sustained, then, over time, a fleet can go from being very reliable to one that is struggling to meet operational needs. We examined whether National Defence appropriately allocated and monitored financial resources to maintain and repair its military aircraft, ships, and land vehicles to meet operational and training requirements.
- **5.15** Funds to maintain and repair National Defence's military aircraft, ships, and land vehicles come from different budgets within the

Department. The largest is the National Procurement (NP) budget, managed by the Assistant Deputy Minister (Materiel). This budget provides for the purchase of spare parts, maintenance equipment, and contracted services for third- and fourth-line activities, as well as limited first- and second-line activities. Although portions of the overall NP budget are allocated to the procurement of ammunition, common equipment such as clothing, and other miscellaneous purchases, this chapter is strictly concerned with the portion allocated to maintenance and repair activities. In the 2009–10 fiscal year, about \$1.8 billion of the total NP budget was spent on maintenance and repair activities. The total amount allocated by the Department to the NP budget is not fixed. The amount specifically allocated for maintenance and repair fluctuates year to year. Exhibit 5.1 presents the NP allocations for the 2006–07 to 2010–11 fiscal years.

5.16 Over the past several years, funds allocated by National Defence did not cover the expressed demand for maintenance and repair activities. The size of the gap between demand and NP funding has been relatively consistent in recent years. The government noted in its 2008 *Canada First* Defence Strategy that the financial resources allocated to the NP budget covered only 70 percent of demand in recent years, significantly impeding the Canadian Forces' ability to train personnel and to maintain high readiness levels.

Exhibit 5.1 Allocated funds have not covered the cost of demands for maintenance and repair activities for the past five fiscal years



Source: Prepared based on National Defence documents

Financial resources for maintenance and repair activities were allocated to priorities

- 5.17 According to the Treasury Board of Canada Secretariat Guide to Management of Materiel (2008), effective planning and resource allocation are essential for delivering a program, for achieving value for money, and for sound stewardship. In this context, we examined whether the Army, Navy, and Air Force equipment program management divisions had established priorities for maintenance and repair of their military equipment, and whether National Defence had allocated financial resources based on these priorities.
- 5.18 The annual planning cycle for the NP budget is an elaborate process that involves many individuals and different organizations within the Department, under the leadership of the Materiel Group. The objective of this process is to allocate available funds among the different maintenance and repair activities. At the beginning of the planning cycle, the equipment program management divisions of the Air Force, Army, and Navy are notified of a preliminary amount of NP funding (known as the planning allocation), which they subsequently allocate to their various fleets. Specific needs and their level of priority are then reviewed by various planning committees, and included in a business plan. These business plans provide estimated cost demands for each priority, expressed by fleet. The demands are based on historical usage, planned usage, and known and anticipated special requirements.
- 5.19 The business plans feed into the deliberations of the National Procurement Oversight Committee. The Committee's mandate is to provide strategic advice and make recommendations to the National Defence Program Management Board—a committee of the most senior managers who provide advice and guidance on resource management—on major NP activities, plans, and policies and to facilitate their implementation. The final decisions on NP allocations for the next fiscal year are taken by the Defence Finance Committee, an advisory body that provides high-level strategic financial guidance to the Deputy Minister.
- 5.20 Overall, in our view, the NP planning process provides an effective forum for discussing needs and priorities with a wide range of personnel responsible for maintaining and repairing military equipment, as well as those who use such equipment for operational and training purposes. We found that the equipment program management divisions of the Army, Navy, and Air Force had each defined their maintenance and repair priorities in their respective business plans for the 2010–11 fiscal year.

The final allocation decisions generally reflected these priorities. The business plans also identified the potential impacts of not funding their priority activities, such as reduced purchase of spare parts, deferred maintenance and repair activities, and reduced operational output (for example, flying hours).

5.21 During the year, circumstances can change, and some planned activities may be either postponed or cancelled. In response, financial resources must be reallocated and used before the end of the fiscal year; otherwise, they will lapse. We observed that processes are in place to reallocate funds that become available during the year. A review takes place regularly to assess the availability of funds, and to identify funds that are unlikely to be spent by year-end. In these cases, a decision can be made to cancel or to postpone an activity to a future year, and to reallocate the funds to another current-year activity. When funds cannot be spent before the end of the fiscal year, managers try to reallocate to other priority activities that can be rapidly undertaken before year-end. However, the reallocation of funds does not always result in complete spending by year-end. For the 2010–11 fiscal year, National Defence estimated that it was unable to spend \$193 million of NP funding dedicated to maintenance and repair.

Total cost information on maintenance and repair is missing

- 5.22 The Treasury Board Policy on Management of Materiel (2006) requires that a materiel management information system be in place to collect and generate complete and accurate data on materiel assets. Such a management information system should be integrated with departmental financial information systems, and should support timely and informed materiel management decisions. We examined whether National Defence has an integrated asset management system to collect and use financial information required to support resource allocation decisions for its maintenance and repair activities.
- 5.23 To support informed decisions about where to allocate overall financial resources for maintenance and repair activities, National Defence must have, among other things, reliable information on the total costs of these activities. For example, having total cost information can help the Department determine whether it would be more cost-effective to assign maintenance and repair tasks for a given fleet to the private sector, rather than to retain the required in-house capacity. Having total cost information on specific fleets can also enable the Department to determine when it will become more cost-effective to replace a fleet, rather than to continue to maintain it. The need for reliable total cost information is heightened by the fact that

National Defence has indicated that it is likely that its long-term investment plan for new equipment has allocated insufficient funds for equipment life-cycle costs.

- **5.24** In general, assessing the total costs of maintenance and repair activities for the Department as a whole or for individual military fleets involves determining the costs of
 - the salaries of all personnel (civilians, regular forces, and reserve forces) involved in planning and executing maintenance and repair;
 - contracted services (which may include provision of spare parts);
 - acquiring spare parts through the central Canadian Forces supply system or locally, through a base's budget;
 - · maintaining the required facilities; and
 - specialized maintenance and test equipment.
- **5.25** While National Defence has tools to estimate the costs of maintenance and repair activities, we found that it does not track the total actual costs of these activities for the Department as a whole or for specific fleets. These costs cannot be readily determined, to a large extent because the Department has not yet put in place adequate information systems. For example, the salaries of most personnel are not captured by the Department's various current asset management information systems. Other maintenance and repair costs, like those related to infrastructure, are also not captured.
- **5.26** In addition to the NP budget, each Canadian Forces base dedicates a portion of its operations and maintenance budget to support first- and second-line maintenance and repair activities. These base expenditures add up to several hundred million dollars per year. However, because base-level maintenance and repair expenditures are not accounted for by fleet, exact figures are not available.
- 5.27 The National Procurement Oversight Committee has acknowledged the lack of good financial information for decision making. This issue is not new. In our 2001 audit, we concluded that National Defence needed to improve its management information systems, and the quality of data they contained. The Materiel Acquisition and Support Information System (MASIS) project, intended to fill this need, was launched in September 1999. At the time of our 2001 audit, National Defence had expected to fully implement MASIS across the Canadian Forces by 2004, and had indicated that it had made this implementation a priority.

- 5.28 By April 2010, MASIS had not been fully implemented across the Canadian Forces. It was then merged with the Department's Financial Management Accounting System (FMAS) to become the Defence Resource Management Information System (DRMIS). Although this merging represents an important step toward implementing an integrated asset management information system, its full potential will not be realized until all Canadian Forces bases have transitioned to the new system, personnel have been adequately trained, and analytical tools to derive useful trend information have been implemented.
- 5.29 National Defence now expects the DRMIS system to be introduced on all Canadian Forces bases by mid-2012. Based on the experience with MASIS, in our opinion, fully implementing DRMIS will likely take many years and will require sustained efforts on a priority basis. In the meantime, in our opinion, the absence of complete, actual, and reliable overall and fleet-specific cost information impedes National Defence's ability to make informed decisions regarding the allocation of funds for the maintenance and repair of its military equipment or to analyze options related to the lifecycle management of its fleets. Ultimately, the Department does not have a firm basis on which to determine whether it is putting enough funding into maintenance and repair activities each year. In our view, this lack of information, coupled with the funding gap, creates a risk that, over time, the Canadian Forces may not be able to maintain all of its current capabilities and therefore may be limited in the size and variety of missions it can undertake.
- **5.30** Recommendation. National Defence should ensure that it develops the ability to produce overall and fleet-specific total cost information for its maintenance and repair activities. These costs should include, at a minimum, expenses related to personnel, contracted services, spare parts, maintenance equipment, and infrastructure.

The Department's response. Agreed. Project Management Office (PMO) MASIS is rolling out Systems, Applications, and Products (SAP) in support of maintenance of weapon systems and equipment. The SAP system, called the Defence Resource Management Information System (DRMIS), is currently in place for over 90% of the Army and Navy, and approximately 10% of the Air Force. There are plans to implement DRMIS in the remainder of the Canadian Forces and this system has the capacity to meet the information requirements identified in this recommendation. This is planned for completion by December 2013.

The MASIS Phase V on-going project has integrated spares inventory with procurement, financial and maintenance engineering data under a single platform. This integration paves the way to equipment, fleet and overall cost reporting. As the implementation of MASIS progresses, personnel, spare parts and procurement costs are being captured. At this time, infrastructure cost is not captured in MASIS, but will be in the future as the Department continues to advance its Enterprise Resource Planning strategy and its SAP implementation.

In parallel, the Repair and Overhaul business process involving the management of the repair line will be assessed against best industry practices to determine the improvements required to optimize this part of the supply chain. This will take place prior to MASIS Phase V blueprinting for repairs and overhaul scheduled in the fall of 2011.

The Maritime equipment program management division is actively moving towards a class-focused program that will improve the ability to capture total maintenance and repair costs for each class of naval platform.

Finally, the work being conducted in developing costing tools and guidelines in response to the Auditor General's audit report on the Acquisition of Military Helicopters will also assist in meeting this recommendation.

National Defence needs better performance information

- **5.31** The Treasury Board Policy on Management of Materiel (2006) states that departments should ensure that their materiel management framework provides them with relevant performance information, and supports informed decision making. We examined whether National Defence collected and used the performance information it requires to support financial resource allocation decisions for its maintenance and repair activities.
- 5.32 National Defence does gather some information about the utilization rates or state of its military equipment. For example, the Air Force gathers data on the number of hours of flying per year, the Navy collects data on days at sea and state of readiness of each ship, and the Army measures the percentage of vehicles that are not serviceable.

- 5.33 The stated purpose of NP expenditures is to keep military equipment at a planned state of readiness. The primary indicator that National Defence uses to measure the performance of the NP allocations is the actual readiness status—that is, the current state of an item of equipment or a fleet measured against its expected readiness level. In our opinion, however, readiness status is not a meaningful or sufficient performance indicator for three reasons. First, quantifiable readiness targets do not exist for all fleets of military equipment. Also, whether or not readiness targets are being met is influenced by factors other than NP funding, such as the availability of personnel. Most importantly, readiness targets for many fleets are based on existing capacity and capability; they have been developed on the basis of what is achievable, not what is needed to meet expected mission and training requirements. In practice, over time, some readiness targets have been downgraded to meet the capacity that is affordable under available funds. In effect, this means that NP funding will generally be sufficient to meet readiness targets, because the targets are related to the availability of funds.
- 5.34 For maintenance and repair work that is contracted to private sector firms, National Defence sets and measures performance indicators, such as turn-around time for repairs, the availability of spare parts, and the reliability of repairs. In our view, these are the types of measures that National Defence could apply in its own operations. Although the Department has recognized the need to systematically measure the efficiency and effectiveness of its own equipment management activities, it does not currently do so. The Navy's equipment program management division is now developing a performance management framework that aims to measure support activities, such as provision of spare parts or engineering changes. The Navy expects the framework to help
 - establish the link between maintenance and repair activities and the impact on the state of its fleets, and
 - predict the future state of its fleets.
- **5.35** The above means that National Defence has limited capacity to assess the impact of its annual NP allocation decisions. Together with the lack of total cost information, this means that the Department does not have a firm basis for determining whether the same result could be achieved at less cost or if the same expenditure could achieve better results.

Availability—The proportion of time that a fleet of military equipment is in an operable state (not undergoing maintenance) in relation to the total operational time available during a stated period.

5.36 National Defence is aware that postponing maintenance and repair tasks has immediate consequences, and also creates the risk of future impacts. In 2008, it undertook a one-time study of the impact of the NP funding gap in previous years, which demonstrated that it has had serious impacts on the Air Force, Army, and Navy, such as

- backlogs of required work,
- fewer sea days and flying hours,
- reduced availability of equipment for training activities and operational requirements,
- · more laborious and expensive corrective repairs, and
- reduced life expectancy of military equipment.

However, National Defence does not regularly conduct such studies and does not regularly monitor these impacts; consequently, it does not know the specific long-term impacts created by its estimated funding gap on operations and training activities.

5.37 Recommendation. National Defence should develop and implement a capacity to provide information on the performance and impacts of maintenance and repair activities, their effectiveness, and their efficiency within each of the Army, Navy, and Air Force, using common performance measures where possible.

The Department's response. Agreed. As noted in the previous response, PMO MASIS is rolling out the Defence Resource Management Information System (DRMIS) in support of maintenance of weapon systems and equipment, which will have the capacity to provide the information outlined in this recommendation. This implementation is planned for completion by December 2013.

Business Intelligence specific queries made available through MASIS Phase V enable some searches on equipment and environment-specific performance and measures. Further development is required to introduce advanced queries and tools to enhance this Department's ability to perform forward planning so that overall effectiveness and efficiency are improved. The Department is also pursuing work on the development of performance measures in the area of inventory management.

Contracting approaches for existing equipment

5.38 Treasury Board policies on risk management and management of materiel require federal departments to assess the risks to which their assets and program activities are exposed, and to implement cost-effective measures to control those risks. We examined whether National Defence had designed its contracting approaches to address the key risks to which its military equipment and its maintenance and repair activities were exposed, and whether it had appropriately implemented these approaches.

The Optimized Weapon System Management program was designed to address key risks

- 5.39 National Defence has historically relied on the private sector to maintain and repair various components and systems of its military aircraft, ships, and land vehicles, especially for third- and fourth-line activities. This work has generally been managed with contracts to private sector firms that get paid for the time and materials needed to complete prescribed inspections and repairs; this approach is known as the traditional approach. Because complex military equipment can have thousands of components, hundreds of contracts were sometimes required to maintain a single fleet. In the 1990s, the Department was managing thousands of these "time and materials" contracts every year. Following significant staff cuts in the mid-1990s, National Defence recognized that its traditional approach to contracting would no longer be sustainable, because it would not have the personnel needed to manage all the contracts.
- 5.40 During the same period, National Defence recognized that the traditional approach had often resulted in unsatisfactory performance and poor contractor accountability, which put at risk the availability of military equipment. For example, several contracted aerospace firms were often late in completing aircraft maintenance and repair activities, which diminished the availability of the aircraft for operations and training activities.
- 5.41 As it looked for solutions to these problems, the Department became interested in new contracting approaches employed by the militaries in the United States, the United Kingdom, and Australia to reduce costs and improve performance. Known as "performance-based logistics" and sometimes called "contracting for availability," these approaches set measurable performance targets (such as turn-around time for repairs, quality of work performed, and availability of spare parts) and provide financial incentives for private sector firms to meet or surpass these targets.



CC-130 Hercules



CP-140 Aurora

- **5.42** In 1998, the Air Force took the lead in designing a new contracting strategy for its main existing fleets. This effort led to the adoption of the Optimized Weapon System Management (OWSM) approach in 2002, with the intent to
 - move from having many short-term contracts to fewer long-term contracts,
 - decrease the number of civilian and military personnel needed to manage and execute maintenance and repair activities,
 - transfer more responsibility to the private sector, and
 - establish performance objectives for private sector firms and provide incentives to improve performance and reduce costs.

5.43 Exhibit 5.2 presents OWSM's main characteristics, as compared to the traditional approach. The Aerospace Equipment Program Management Division (Air Force) under the Assistant Deputy Minister (ADM) for Materiel was responsible for the development of the OWSM program. By bundling hundreds of traditional maintenance contracts under only a few OWSM contracts, and by offering incentives to private sector firms, the Department expected to improve the firms' accountability for performance. The OWSM directive also required internal project teams to generate 15 percent cost savings compared to the annual fleet support costs of their previous maintenance approach. Overall, we found that the OWSM contracting approach was designed to address the key pressures and risks facing the Air Force's maintenance and repair activities.

Exhibit 5.2 Two new contracting approaches have introduced significant changes within National Defence

	Traditional approach	Optimized Weapon System Management approach	In-Service Support Contracting Framework approach
Applies to	Many existing fleets	Several existing fleets	All new fleets
Number of contracts	Hundreds of support contracts per fleet	1 to 5 support contracts per fleet	1 support contract per fleet, established at fleet acquisition
Level of application	Component level (e.g. radar)	Major system level (e.g. avionics)	Fleet level (e.g. aircraft)
Contract type	Time and materials	Performance-based, with incentives; fixed price where possible	Performance-based, with incentives; fixed-price
Contract term	1 year	5+ years	20+ years
Required management resources	Large departmental management staff required	Moderate departmental management staff required	Smaller departmental management staff required

Source: National Defence





CF-18 Hornet

Implementing new contracting approaches for existing equipment has been slower and more limited than intended

- 5.44 In 2002, the OWSM program was to be applied to four Air Force fleets that could benefit from the new approach: they had high annual maintenance and repair costs and enough years of useful life left to justify the initial investments in the program. These fleets were the Hercules transport airplane, the Aurora maritime patrol airplane, the Griffon helicopter, and the CF-18 jet fighter. The objective was to put in place by December 2005 nine contracts to support these four fleets. We examined whether National Defence had met its target dates for the establishment of these contracts. Where contracts were signed, we examined whether they included the required elements, as set out in internal guidance.
- 5.45 Three of the nine planned contracts were awarded by the original target date of December 2005 (Exhibit 5.3). According to National Defence, these OWSM contracts have led to performance improvements, such as faster maintenance turn-around times, increased aircraft availability, and improved management of spare parts. Two of the nine planned contracts were awarded in late 2010 and early 2011. As of April 2011, the remaining four contracts had yet to be awarded.

Exhibit 5.3 Only three of nine contracts were awarded by the target date

Aircraft	Type of contract	Contract awarded by target date of December 2005: date of award	Contract awarded after target date of December 2005: date of award	Contracts still not awarded as of 30 April 2011
	Airframe	October 2005		
CC-130 Hercules	Avionics			Contract pending
	Engines*			Contract pending
CF-18 Hornet	Airframe			Contract pending
	Avionics		October 2010	
	Engines			Contract pending
CP-140 Aurora	Airframe	June 2005		
	Avionics	June 2005		
	Engines*			Contract pending
CH-146 Griffon	All systems		January 2011	
Total		3	2	4*

^{*}The CC 130 Hercules and the CP 140 Aurora use the same engine model. A single engine maintenance contract is being sought for both fleets

Source: Prepared based on National Defence documents

Airframe—The structural components of an aircraft, such as fuselage, empennage, wings, and landing gear, but excluding propulsion (engines, rotor, or reactors), electronics systems, and any mounted weapon.

- 5.46 Although the five contracts that we reviewed generally included the expected OWSM contract elements, we found that the incentive and penalty clauses called for in the OWSM framework have so far been fully implemented only in the case of the Hercules airframe contract. Since the incentives in OWSM contracts are intended to drive better performance, which translates into increased availability of fleets, delays in their implementation mean that the expected program benefits will not be realized to their full extent.
- 5.47 The Air Force established a board of directors to review progress on OWSM program implementation and related organizational changes. Housed within the Aerospace Equipment Program Management Division, the Board started operating in 2003 and met regularly in 2003, 2004, and 2005 to review progress and provide management attention and oversight. Meetings became less frequent starting in 2006, following the departure of the program leader, and the last one was held in February 2009. As a result, oversight by the Board has diminished.
- 5.48 Over the years, National Defence has identified several challenges that contributed to delays in the OWSM program implementation:
 - Resistance to change. The OWSM approach entailed significant changes in the roles and responsibilities of officials working in equipment program management divisions. The required culture change has faced resistance and has been slow to happen.
 - Lack of capacity. OWSM implementation required new, specialized skills for contract management that often did not exist in project teams. Training to develop the required skills was insufficient, and the high turn-over rate of military personnel did not favour skill retention within project teams. In addition, personnel numbers were often insufficient to undertake planned tasks.
 - Approval processes. Completing the work necessary to seek approval from the Treasury Board of Canada sometimes took longer than planned. In 2009, National Defence was required to complete a study of the potential impacts on the projected CF-18 OWSM contract on Canadian small and medium enterprises. National Defence did not seek contract approvals until the study was completed in 2010.
 - Negotiations with private sector firms. The OWSM approach was new for private sector firms, and they had to adapt to it, too. In certain cases, firms have been reluctant to adopt the new approach, and this reluctance has made negotiations more difficult.

- 5.49 We are concerned that a lack of capacity within the Aerospace Equipment Program Management Division and the reduced activity of the OWSM Board of Directors in recent years mean that current and planned OWSM contracts will not be completed and implemented as expected. Given that the Aurora, Hercules, and CF-18 fleets are all scheduled to be retired between 2014 and 2020, only a few years remain for the Air Force to derive benefits from the implementation of these contracts.
- 5.50 Of greater concern is the lack of concerted action across the Canadian Forces to implement new contracting approaches for existing equipment. The Navy and Army were facing similar staffing pressures as the Air Force a decade ago. Indeed, in 2004, National Defence's Materiel Group developed a concept for operations that aimed to provide consistency in rolling out an OWSM approach across the Canadian Forces. We could find no evidence that this concept was implemented. Neither the Navy nor the Army adopted a formal program or directive to require their equipment program management divisions to review or change their maintenance and repair contracting approaches. Rather, the decision to adopt or not to adopt a performance-based approach for a given fleet has remained the prerogative of the responsible equipment program management teams.
- 5.51 In one instance, an Army management team used a contracting approach similar to OWSM to support its several fleets of wheeled light armoured vehicles. As explained in the Case Study on a new contracting approach, the Army claims to have achieved positive results with the performance-based contract it set up for these fleets in 2004. The Navy also has some experience with long-term maintenance contracts for the maintenance of its minor vessels, including the Kingston class of maritime coastal defence vessels. However, these contracts were not performance-based, and did not include the incentive clauses that characterize OWSM contracts.
- 5.52 In our opinion, the lack of concerted action and follow-through has resulted in slower and more limited implementation than planned of the new contracting approach for existing military equipment and related contracts. Further, we believe that implementation has relied too much on the initiative of selected individuals. As a consequence, National Defence has lost opportunities to derive the potential benefits of improved performance, improved accountability, and reduced costs. Reducing costs, in particular, might have helped to reduce the financial gap between demands for maintenance and repair and available funding.

Case Study—A new contracting approach has led to improved availability of wheeled light armoured vehicles

The Army owns more than 1,000 wheeled light armoured vehicles of different models, including the Bison, the Coyote, the Light Armoured Vehicle III, and the armoured patrol vehicle. All of them entered service between 1990 and 2006.

Prior to 2004, the Army's maintenance and repair approach for these fleets was based on the traditional model: private firms were retained for third- and fourth-line services through time



Light armoured vehicle

and materials contracts. This approach proved to be inefficient, creating a significant backlog of engineering issues.

In 2004, the Army applied principles similar to those of the Air Force's Optimized Weapon System Management program and awarded General Dynamics Land Systems—Canada (GDLS), a specialized Canadian defence company, a three-year sole-source, performance-based contract with two one-year options, for an initial maximum value of \$392 million. Third- and fourth-line work was then centralized in two separate locations, with the Army's Montreal workshop depot kept as a strategic backup in the event that demand temporarily exceeded GDLS's capacity. In addition to carrying out maintenance and repair work, GDLS was responsible for managing suppliers and subcontractors, as well as for providing training to National Defence personnel.

The contract was renewed in 2008 for another five years, with 21 one-year options to be granted one year at a time if the company meets specified performance targets. The total maximum value of this second contract, over 26 years, is about \$3.1 billion.

According to National Defence, the contract has resulted in significant performance improvements. For example, the percentage of on-time delivery for spare parts has increased from an average of 75 percent in 2006 to 94 percent in 2009, and the percentage of on-time repair and overhaul projects has increased from an average of 13 percent in 2006 to 97 percent in 2009. The observed reduction of delays has led to increased availability of wheeled light armoured vehicles.

Source: Prepared based on National Defence documents

5.53 Recommendation. National Defence should review its Optimized Weapon System Management (OWSM) concept for operations, formally assess whether OWSM should be pursued for other existing fleets, and document its decision for each fleet. For fleets where OWSM will be pursued, actions should be taken to ensure prompt and complete implementation in accordance with the Department's plans and priorities.

The Department's response. Agreed. National Defence will review the OWSM Concept of Operations and update it as required by July 2012. National Defence will then investigate the feasibility of implementing OWSM to other existing fleets.

Demonstrating cost savings is a challenge for the Optimized Weapon System Management program

- 5.54 One of the objectives of the OWSM program was to reduce the costs of maintenance and repair contracts. The program directive fixed a target of 15 percent savings on maintenance and repair contract costs for selected Air Force fleets. This potentially represented hundreds of millions of dollars in savings over many years. We examined whether the Air Force had achieved this target through OWSM program implementation.
- Defence reported that its OWSM approach had lowered fleet support costs. However, National Defence was unable to provide complete information to us to support this assertion, primarily because of the lack of reliable baseline cost information. As explained in paragraphs 5.27–5.29, National Defence has not yet fully implemented an integrated asset management information system that would provide it with the cost information it needs to do a before and after comparison. Other factors make comparisons difficult, including aging equipment, changing fleet size, the transfer of new responsibilities to the private sector, and the fact that the Department does not generally consider the cost of its own personnel's salaries when accounting for its maintenance and repair costs. In our opinion, implementing our recommendation in paragraph 5.30 would allow National Defence to develop reliable baseline cost information for its military fleets.

Contracting approaches for new equipment

- 5.56 In 2005, National Defence started to formally develop a contracting approach for maintenance and repair of new fleets of military aircraft, ships, and land vehicles. The resulting In-Service Support Contracting Framework (ISSCF) has been applied as policy under the Assistant Deputy Minister (ADM) for Materiel since July 2008, and became a departmental directive in August 2010.
- 5.57 The ISSCF has been developed with the intention of furthering the changes that began under the Optimized Weapon System Management (OWSM) program. Under the ISSCF, there is only one prime contractor per fleet, who is awarded both the acquisition and in-service support contracts to create a single point of accountability. The original equipment supplier is the prime contractor by default. The contracted in-service support period can extend up to 20 years, and the contract will include many fixed-price elements. Additional responsibilities, such as the ownership and management of spare parts,

In-service support — Activities required to sustain the operation of a military fleet over its lifetime, including engineering, training, inspection, maintenance and repair of equipment, and provision of spare parts.

and the management of all subcontractors, are transferred to the prime contractor. Exhibit 5.2 compares the ISSCF characteristics to those of the OWSM and traditional approaches.

- 5.58 The ISSCF has been formally applied within ADM (Materiel) since July 2008, although National Defence had applied some of the Framework's principles in several acquisition projects before then. Since 2008, two new military fleets have been acquired and subjected to the ISSCF process. Project teams within National Defence are currently working on the development of in-service support concepts, pursuant to the ISSCF, for numerous other planned equipment acquisitions.
- 5.59 The first of the two recent acquisitions is a new fleet of 17 CC-130 Model J Hercules transport planes, first contracted in 2007, and for which deliveries started in 2010. In this case, a contract amendment worth \$723 million was awarded in 2009 to provide for maintenance and repair services until mid-2016. The Case Study on the Hercules fleets illustrates how maintenance arrangements for the Air Force's old and new Hercules aircraft have evolved over time.
- 5.60 The second recent acquisition is a new fleet of 15 Chinook helicopters, contracted in 2009, with first delivery expected in 2013. The acquisition contract for this fleet includes provisions for 20 years of in-service support. Pricing negotiations for these provisions are scheduled for completion in 2013; their estimated value is several billion dollars. Other acquisition projects are currently under way but, overall, experience with ISSCF implementation remains limited at this point.

While In-Service Support Contracting Framework's risks have been identified, mitigation measures are limited

5.61 By favouring the original equipment supplier as the prime contractor for maintenance and repair services, and by combining acquisition and support contracts into a single procurement process, the ISSCF significantly changes the procurement process for these services and introduces new risks, as identified by National Defence. We examined whether National Defence designed the ISSCF to address key risks related to its maintenance and repair activities, and whether it adequately assessed and managed the risks associated with the approach.

Case Study—The maintenance approach for the Hercules fleet has evolved over the years to meet changing needs

CC-130 HERCULES - Models E and H

National Defence has operated fleets of CC-130 Hercules transport aircraft for over 50 years. Various Hercules models have been used during that time. In early 2011, the fleet included 29 active aircraft of three different models. Models E and H were acquired in 1960 and 1996, respectively, and will be retired by 2012 and 2017, respectively.

For decades, National Defence has relied on a combination of in-house capacity and contracted services to maintain and repair its fleets of Hercules aircraft. First- and second-line work was usually carried out by National Defence staff, while third-line work was usually conducted by private sector firms under traditional time and materials contracts. National Defence managed the supply chain for spare parts and was responsible for engineering modifications and configuration management, among other tasks.

In the early 2000s, faced with declining fleet availability, National Defence decided to change its maintenance and repair approach for Models E and H, and made plans to transfer third-line work for the airframe, the engines, and the avionics systems to Optimized Weapon System Management (OWSM) performance-based contracts. The Department has since transitioned to the OWSM approach for airframe maintenance, but contracted work for the engines and the avionics systems is still managed under more than 20 traditional contracts.

The OWSM airframe contract was awarded in 2005 to Cascade Aerospace, a Canadian company, for five and a half years. Under this contract, worth about \$423 million, the contractor has incentives to meet performance targets that are defined each year in an annual operating plan. Twice a year, a contract performance review board assesses the contractor's performance, and decides whether a performance bonus or penalties are warranted. In 2010, the contract was renewed for an additional five-year term, based on good performance results.

CC-130 HERCULES - Model J

In 2007, National Defence contracted Lockheed Martin, an American aerospace company, to provide it with 17 new Model J aircraft, which will gradually come into service between 2010 and 2012. This new Hercules fleet will be maintained under an In-Service Support Contracting Framework (ISSCF) contract. This in-service support contract, which has a maximum value of \$723 million, was awarded to Lockheed Martin in 2009, and will extend until mid-2016, with potential optional years beyond that.

Under this contract, National Defence remains responsible for the first line of maintenance and portions of the second line, while the contractor has responsibility for the remaining second-line activities, as well as for all third-line maintenance and repair work for all systems. The contractor is also responsible for the supply chain, the management of all subcontractors, and in-service support for the Department's training facility. This arrangement provides National Defence with a single point of accountability for aircraft maintenance and repair.

When fully implemented, this contract structure will enable National Defence to hold the contractor accountable for aircraft availability. The contractor will be required to provide an annual average of 11.5 planes out of 17 (68 percent) per day. The contractor's performance will be measured against this standard, and once a year, this performance will be assessed to determine whether any of the penalties defined in the contract need to be applied. National Defence personnel will retain responsibilities for contract oversight and strategic decisions.

Source Prepared based on National Defence documents

- 5.62 The ISSCF development started in 2005, supported by personnel who had experience with the OWSM approach. Essentially, National Defence developed the ISSCF as the logical extension of OWSM to apply to new acquisitions. We found that rather than conducting a new analysis of the risks to maintenance and repair activities, the Department accepted that the previously identified pressures and risks that gave rise to the OWSM program were still valid: traditional time and materials contracts did not promote innovation and high performance in industry, lacked sufficient accountability, were resource intensive for the Department to manage, and had proven to be operationally ineffective, often resulting in poor equipment availability.
- 5.63 National Defence acknowledges that the ISSCF is based in part on untested concepts related to long-term performance-based contracts, and reliance on a single point of accountability for maintenance and repair performance and fleet availability. The Department identified a number of new risks created by the ISSCF itself, recognizing that it could have unforeseen and unintended adverse consequences. These risks include
 - loss of work traditionally conducted in Canada if ISSCF contracts are awarded to foreign suppliers;
 - total dependency on one supplier for each fleet;
 - reduced financial flexibility and ability to change requirements and priorities as needed, because of long-term, fixed-price contracts;
 - loss of skills and expertise required to assess value for money and industry proposals, resulting from the transfer of responsibilities to the private sector;
 - overpayment for services, especially in a directed contract situation; and
 - uncertainty that the required culture change will be successful within federal departments faced with having to adapt to the new contracting approach.
- 5.64 The ISSCF includes some potential measures to mitigate these identified risks. While some of these measures are within National Defence's control, others, such as the ISSCF's call for developing a culture change plan for the Government of Canada, depend on the authority and collaboration of other federal organizations: And still others, such as the training of civilian and military personnel by the original equipment supplier, depend on industry. While some measures have already been acted upon, others are still at the planning stage, or will be implemented only when new acquisition contracts are awarded.

Directed contract—A federal government contract awarded to a preselected contractor when the contracting authority can justify setting aside the requirement to solicit competitive bids.

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- 5.65 Although we recognize that ISSCF implementation is still in its early days, we are concerned that some risks may not be sufficiently mitigated by the identified measures. For example, a risk exists that long-term contracts could limit the Department's financial and operational flexibility to adapt to changing circumstances in the future. Inflexible, fixed-price long-term contracts for specific fleets may reduce the amount of funding available for other fleets. We asked the Department to provide us with more information on the discussions and analysis that were related to the risk of reduced financial flexibility. Officials told us that discussions had been held on this topic at senior levels, and that the ISSCF had been modified to require that contracts be flexible by including predetermined maintenance and repair costs for increasing or decreasing levels of equipment usage (for example, yearly flying hours). However, no detailed financial analysis was prepared to support the risk analysis in this area. Considering the potential consequences that a loss of financial flexibility in the National Procurement budget could have on the Department's military capabilities, we are concerned that a comprehensive financial analysis was not undertaken.
- 5.66 More importantly, while processes exist within National Defence to review in-service support concepts for individual projects, we are concerned that there is no departmental forum that provides oversight of overall ISSCF implementation, and that reviews risk mitigation over the long term. In our opinion, National Defence has not demonstrated that it is sufficiently monitoring and mitigating key risks, like the risk of losing important maintenance and repair expertise within the Department, nor is it providing sufficient assurance that these risks will be adequately mitigated. Reducing ISSCF risks will be important, given that most of the new major military equipment acquisitions planned under the Canada First Defence Strategy for the next two decades will be subject to ISSCF requirements.
- **5.67 Recommendation.** National Defence should regularly review the In-Service Support Contracting Framework to update its assessment of risks as well as mitigation measures and their status. It should identify specific actions and responsibilities for doing this, and monitor progress on an ongoing and long-term basis.

The Department's response. Agreed. National Defence will examine the ISSCF's risk assessment and mitigation measures with a view towards identifying specific actions that might be warranted, and to establish an ongoing monitoring system by July 2012.

Insufficient resources and oversight threaten implementation of the In-Service Support Contracting Framework

- 5.68 The ISSCF has significant implications for National Defence beyond risk management. For example, implementation requires considerably detailed upfront planning by National Defence personnel, because they need to make projections over a 20-year period, and to consider different scenarios about future fleet usage and maintenance and repair needs. We examined whether National Defence had put in place actions and oversight mechanisms to ensure successful implementation.
- **5.69** To support implementation of the ISSCF by individual project teams, National Defence staff prepared an action plan in 2008. We found that this plan remains unapproved. In addition, because of a lack of assigned resources, many of its action items have not been undertaken or completed, such as
 - developing a model ISSCF contract,
 - drafting a contract performance management framework,
 - preparing a procurement skills development plan, and
 - rolling out a communication plan about ISSCF.

During the course of our audit, the central team responsible to support ISSCF implementation had only two members, only one of whom was assigned full-time.

- 5.70 Regarding oversight mechanisms, project teams for new acquisitions are required to submit in-service support concept proposals for new acquisitions to the Assistant Deputy Minister (ADM) for Materiel for approval. Any deviation from the framework requirements must also be approved. In practice, the proposals have been presented to the Management Group Program Management Committee (MGPMC) chaired by the ADM (Materiel).
- 5.71 To facilitate its oversight of individual proposals, in March 2009 the MGPMC directed that a project review committee be established for the purpose of independently reviewing in-service support concept proposals before they are submitted to the MGPMC. However, this did not happen. In its absence, there is no independent review process to assess in detail whether in-service support concept proposals comply with ISSCF requirements, and to ensure consistency in application.

- 5.72 We reviewed all six presentations made to the MGPMC by acquisition project teams between 2008 and 2011. We noted significant variations related to the level of detail they provided, and to the point in the acquisition process at which they were presented. In several cases, a support concept proposal was approved by the MGPMC, even though the project was still at the conceptual stage and neither the specific type of equipment, nor the manufacturer, had yet been identified. We found that there is no clear guidance about the proper timing for support concepts to be presented to the MGPMC or ADM (Materiel), nor about the need to return to MGPMC or ADM (Materiel) when project details are more fully known, or in the event of significant changes to a procurement project or an in-service support concept.
- 5.73 While the MGPMC reviews and approves proposals on a project-by-project basis, this committee is not dedicated solely to ISSCF implementation. As already noted, there is no departmental forum that provides oversight of ISSCF implementation, like the Board of Directors did for the Optimized Weapon System Management program.
- **5.74** Overall, we are concerned that limited central resources and oversight threaten the successful implementation of ISSCF. We do not believe that ISSCF implementation has received the attention and resources it needs. Our recommendation on the implementation of ISSCF is found at paragraph 5.79.

Coordination with other federal departments and Canadian industry needs to be strengthened

- 5.75 As noted in the Introduction to this chapter, the government plans to spend substantial amounts of money over 20 years on new military fleets and associated maintenance and repair. The Treasury Board Contracting Policy requires that contracting for goods and services be conducted in a manner that will support long-term industrial and regional development. Public Works and Government Services Canada (PWGSC), the department responsible for government contracts, and Industry Canada, responsible for industrial regional benefits, both have roles to play in the procurement of new military equipment. Thus, ISSCF implementation requires collaboration with these federal departments and others, as necessary, to ensure consistent and effective application.
- 5.76 National Defence is expected to have the technical expertise to draft statement of requirements or statement of work that will be used in contractual agreements. The management of a contract is typically

done jointly between National Defence and PWGSC to best benefit from the expertise of both departments. PWGSC, by contrast, is expected to ensure that its staff has the specialized skills required to draft complex performance-based contractual agreements, monitor them over long periods, and effectively challenge claims from contractors, especially in directed contracts, where the risk of paying higher prices is greater. In doing such work, PWGSC must work closely with National Defence. However, National Defence took no action to ensure that PWGSC would be able to support ISSCF implementation as intended. We also noted that, in the internal implementation action plan, resources have not been assigned to any of the identified actions that relate to working with other federal departments.

- 5.77 Beyond federal departments, the ISSCF also has potential implications for the Canadian defence industry. Current trends suggest that more and more responsibility for providing maintenance and repair services is being transferred to the private sector. Thus, it is important that National Defence both understand and support industry capacity. In the course of developing the ISSCF, National Defence informed industry of the direction it intended to take, and made some changes to the framework in reaction to concerns expressed at the time. Notwithstanding, industry associations have more recently expressed concern about designating the original equipment supplier as the default prime contractor for maintenance and repair. Because few manufacturers of military aircraft, ships, and land vehicles exist in Canada, industry is concerned that opportunities for Canadian defence companies will diminish, and that most of the value-added work, like engineering design, will be done outside Canada. National Defence believes that robust application of the government's Industrial Regional Benefits policy will address these concerns. The ISSCF does not include a plan or mechanism to monitor its impact on the Canadian defence industry as implementation proceeds, or to address issues as they arise.
- 5.78 National Defence will need to strengthen internal processes and better coordinate its efforts with other federal departments and the Canadian defence industry to ensure that maintenance and repair contracts for all new acquisitions provide good value for Canadian taxpayers, good results for the Canadian Forces, and good business opportunities for the Canadian defence industry.
- **5.79** Recommendation. National Defence should review and revise the In-Service Support Contracting Framework (ISSCF) governance structure to ensure adequate and timely departmental oversight and control. The Department should adequately resource the specific

actions it has identified that need to be taken to ensure ISSCF's successful implementation, including the need to coordinate its efforts with other federal departments and the Canadian defence industry.

The Department's response. Agreed. By July 2012, National Defence will review its governance structure to ensure adequate and timely visibility and control of: (a) fleet support concepts; and (b) ISSCF institutionalization. National Defence has already identified specific actions that need to be undertaken to ensure successful institutionalization, including the need to coordinate its efforts with other federal departments and Canadian industry; resourcing of those actions is in progress.

Conclusion

- 5.80 We witnessed dedicated military and civilian personnel in the field working diligently to achieve assigned objectives and missions. Our audit determined that National Defence planned and managed the maintenance and repair of military equipment to meet operational priorities in the short term. However, its ability to meet training and operational requirements over the long term is at risk, because of long-standing deficiencies in management information systems, the lack of sufficient cost and performance information, and ongoing weaknesses in the implementation and oversight of its contracting approaches for maintenance and repair services.
- 5.81 Regarding maintenance and repair funding allocations, we determined that National Defence has an effective forum in place to allocate financial resources to defined priorities. However, National Defence has limited ways of assessing the long-term impacts of its annual National Procurement (NP) allocation decisions and lacks important information on total costs and performance of maintenance and repair activities. Without this information, National Defence has a limited basis on which to determine whether it is putting sufficient funding into maintenance and repair activities each year to optimize its support of military equipment over the long term.
- 5.82 Regarding contracting approaches, we found that National Defence did establish maintenance and repair contracting frameworks for its military vehicles, ships, and aircraft in response to risks and pressures it was facing at the time. However, implementation of the Optimized Weapon System Management approach for existing fleets

has been slower and more limited than intended. Consequently, opportunities for improvements have been missed and benefits have been postponed.

5.83 Implementation of the In-Service Support Contracting Framework (ISSCF) for new military equipment is still at an early stage. Many actions needed to ensure successful implementation by individual project teams are yet to be approved, and central resources required for implementation have been limited. Although risks associated with the ISSCF have been identified, many mitigation measures have yet to be put in place, and there is no suitable forum to oversee implementation. Considering the long-term implications and risks for National Defence, other federal departments, and the Canadian defence industry, we do not believe that ISSCF implementation has received the attention and resources it needs to ensure success.

About the Audit

All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by the Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

Objectives

The overall objective of the Audit was to determine whether National Defence planned and managed the maintenance and repair of military aircraft, ships, and land vehicles to meet operational and training requirements.

The two sub-objectives were as follows:

- To determine whether National Defence appropriately allocated and monitored financial resources to maintain and repair its military aircraft, ships, and land vehicles to meet operational and training requirements.
- To determine whether National Defence appropriately established and implemented maintenance and repair contracting approaches for its military aircraft, ships, and land vehicles.

In this audit, "appropriately" means making decisions based on a clearly communicated rationale that takes into account risks and departmental directives.

Scope and approach

Our audit focused on the allocation and management of financial resources for maintenance and repair activities of military equipment, as well as on contracting approaches used by National Defence for maintenance and repair services.

The audit examined how National Defence allocated its financial resources to its priorities for the maintenance and repair of military equipment. Specifically, we examined whether National Defence had systems and practices to provide managers with the information necessary to make decisions about allocating financial resources for maintenance and repair purposes, as well as how this information was used.

The audit also examined how National Defence designed and implemented contracting approaches for the nature ince and repair of military equipment. Specifically, we examined whether National Defence's new contracting approaches were based on a strategic analysis of the risks to which the Department's equipment assets and maintenance program activities were exposed, and whether the risks created by the new approaches were adequately assessed and managed. Finally, we examined whether National Defence had appropriately implemented its new contracting approaches.

The audit examined documents contained in National Defence files, as well as maintenance and repair contracts for military fleets managed under the Optimized Weapon System Management and In-Service Support Contracting Framework approaches. We did not audit the records of private sector firms. Accordingly, our conclusions do not pertain to private sector practices.

During the course of the audit, we conducted over 100 interviews with National Defence officials and Canadian Forces members located in the Department's headquarters in Ottawa or on Canadian Forces bases (CFBs) across Canada. We visited maintenance and repair installations used by the Army (CFB Montreal and CFB Valcartier), the Air Force (CFB Shearwater and CFB Trenton), and the Navy (CFB Esquimalt and CFB Halifax).

We also met with representatives of private sector companies that were awarded long-term maintenance and repair contracts for Canadian Forces aircraft, ships, or land vehicles. As part of this work, we interviewed representatives for associations of Canadian defence and aerospace companies. We did not audit private sector entities.

In addition, we had discussions on maintenance and repair contracting approaches with our counterparts in national audit offices in the United States, the United Kingdom, and the Netherlands. We also had similar discussions with representatives of the defence departments of the United Kingdom and the Netherlands.

The audit did not examine recruitment and retention practices related to maintenance personnel, nor did it examine the management of infrastructure used for maintenance purposes. We did not audit the portions of military equipment acquisition contracts that were not related to maintenance and repair.

Criteria

	ted and monitored financial resources to maintain and repair onal and training requirements, we used the following criteria:	
Criteria	Sources	
National Defence allocates its budgeted resources toward its priorities for the maintenance and repair of military equipment.	Guide to Management of Materiel, Treasury Board of Canada Secretariat	
National Defence has systems and practices that provide information necessary to make decisions about allocating financial resources for maintenance and repair of military equipment.	Policy on Management of Materiel, Treasury Board, 2006	
The Army, Navy, and Air Force manage equipment readiness planning and monitoring to meet operational and training needs.	Guide to Management of Materiel, Treasury Board of Canada Secretariat	
	and implemented maintenance and repair contracting approaches vehicles, we used the following criteria:	
National Defence develops maintenance approaches for the maintenance and repair of military equipment that are based on a strategic analysis of the risks to which the Department's equipment assets and maintenance program activities and interests are exposed.	Policy on Management of Materiel, Treasury Board, 2006 Risk Management Policy, Treasury Board, 1994	
National Defence appropriately implements applicable approaches to maintenance and repair.	The Way Ahead (Optimized Weapon System Management (OWSM) directive and guidance), National Defence	
	In-Service Support Contracting Framework for Canadian Force: Platforms During the Initial Acquisition Stage, National Defence, 2008, 2009	
	Defence Administrative orders and directives 3022-0 and 3022-1, National Defence	

Management reviewed and accepted the suitability of the criteria used in the audit.

Period covered by the audit

Our examination of the management and allocation of the maintenance and repair funds covered the planning cycles for fiscal years 2009–10 and 2010–11. Our examination of contracting approaches covered the decade from 2001 to 2011.

Audit work for this chapter was substantially completed on 30 April 2011.

Audit team

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Appendix List of recommendations

The following is a list of recommendations found in Chapter 5. The number in front of the recommendation indicates the paragraph where it appears in the chapter. The numbers in parentheses indicate the paragraphs where the topic is discussed.

Recommendation

Response

Allocation and monitoring of financial resources

5.30 National Defence should ensure that it develops the ability to produce overall and fleet-specific total cost information for its maintenance and repair activities. These costs should include, at a minimum, expenses related to personnel, contracted services, spare parts, maintenance equipment, and infrastructure. (5.14–5.29)

Agreed. Project Management Office (PMO) MASIS is rolling out Systems, Applications, and Products (SAP) in support of maintenance of weapon systems and equipment. The SAP system, called the Defence Resource Management Information System (DRMIS) is currently in place for over 90% of the Army and Navy, and approximately 10% of the Air Force. There are plans to implement DRMIS in the remainder of the Canadian Forces and this system has the capacity to meet the information requirements identified in this recommendation. This is planned for completion by December 2013.

The MASIS Phase V on-going project has integrated spares inventory with procurement, financial and maintenance engineering data under a single platform. This integration paves the way to equipment, fleet and overall cost reporting. As the implementation of MASIS progresses, personnel, spare parts and procurement costs are being captured. At this time, infrastructure cost is not captured in MASIS, but will be in the future as the Department continues to advance its Enterprise Resource Planning strategy and its SAP implementation.

In parallel, the Repair and Overhaul business process involving the management of the repair line will be assessed against best industry practices to determine the improvements required to optimize this part of the supply chain. This will take place prior to MASIS Phase V blueprinting for repairs and overhaul scheduled in the fall of 2011.

The Maritime equipment program management division is actively moving towards a class-focused program that will improve the ability to capture total maintenance and repair costs for each class of naval platform.

Finally, the work being conducted in developing costing tools and guidelines in response to the Auditor General's audit report on the Acquisition of Military Helicopters will also assist in meeting this recommendation.

Recommendation

5.37 National Defence should develop and implement a capacity to provide information on the performance and impacts of maintenance and repair activities, their effectiveness, and their efficiency within each of the Army, Navy, and Air Force, using common performance measures where possible. (5.31–5.36)

Response

Agreed. As noted in the previous response, PMO MASIS is rolling out the Defence Resource Management Information System (DRMIS) in support of maintenance of weapon systems and equipment, which will have the capacity to provide the information outlined in this recommendation. This implementation is planned for completion by December 2013.

Business Intelligence specific queries made available through MASIS Phase V enable some searches on equipment and environment-specific performance and measures. Further development is required to introduce advanced queries and tools to enhance this Department's ability to perform forward planning so that overall effectiveness and efficiency are improved. The Department is also pursuing work on the development of performance measures in the area of inventory management.

Contracting approaches for existing equipment

5.53 National Defence should review its Optimized Weapon System Management (OWSM) concept for operations, formally assess whether OWSM should be pursued for other existing fleets, and document its decision for each fleet. For fleets where OWSM will be pursued, actions should be taken to ensure prompt and complete implementation in accordance with the Department's plans and priorities. (5.38–5.52)

Agreed. National Defence will review the OWSM Concept of Operations and update it as required by July 2012. National Defence will then investigate the feasibility of implementing OWSM to other existing fleets.

Contracting approaches for new equipment

5.67 National Defence should regularly review the In-Service Support Contracting Framework to update its assessment of risks as well as mitigation measures and their status. It should identify specific actions and responsibilities for doing this, and monitor progress on an ongoing and long-term basis. (5.56–5.66)

Agreed. National Defence will examine the ISSCF's risk assessment and mitigation measures with a view towards identifying specific actions that might be warranted, and to establish an ongoing monitoring system by July 2012.

Recommendation

5.79 National Defence should review and revise the In-Service Support Contracting Framework (ISSCF) governance structure to ensure adequate and timely departmental oversight and control. The Department should adequately resource the specific actions it has identified that need to be taken to ensure ISSCF's successful implementation, including the need to coordinate its efforts with other federal departments and the Canadian defence industry. (5.68–5.78)

Response

Agreed. By July 2012, National Defence will review its governance structure to ensure adequate and timely visibility and control of: (a) fleet support concepts; and (b) ISSCF institutionalization. National Defence has already identified specific actions that need to be undertaken to ensure successful institutionalization, including the need to coordinate its efforts with other federal departments and Canadian industry; resourcing of those actions is in progress.

Report of the Auditor General of Canada to the House of Commons—Fall 2011

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Report of the
Auditor General
of Canada
to the House of Commons

FALL

Matters of Special Importance Main Points—Chapters 1 to 5 Appendices



Office of the Auditor General of Canada



2011



Report of the Auditor General of Canada

to the House of Commons

FALL

Matters of Special Importance
Main Points—Chapters 1 to 5
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Office of the Auditor General of Canada

The Fall 2011 Report of the Auditor General of Canada comprises Matters of Special Importance, Main Points—Chapters 1 to 5, Appendices, and five chapters. The main table of contents for the Report is found at the end of this publication.

The Report is available on our website at www.oag-bvg.gc.ca.

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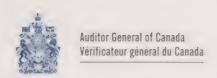
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To the Honourable Speaker of the House of Commons:

I have the honour to transmit herewith this 2011 annual report to the House of Commons, which is to be laid before the House in accordance with the provisions of subsection 7(3) of the *Auditor General Act*.

John Wiersema, FCA

Interim Auditor General of Canada

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Matters of Special Importance—2011



Matters of Special Importance—2011

I am pleased to present this report to Parliament, covering a range of matters that indicate the diversity of activities in which the federal government engages on behalf of Canadians:

- implementing Canada's Economic Action Plan;
- issuing visas for entry into Canada;
- making income support payments to agricultural producers;
- · regulating pharmaceutical drugs; and
- maintaining and repairing military equipment.

My appointment as Interim Auditor General of Canada was recent and my tenure will be brief. Nonetheless, my 33 years in the Office provide a vantage point from which I have observed that government programs and initiatives must have certain fundamental elements to be successful. They include

- clarity of purpose,
- · committed and sustained leadership,
- predictable and stable funding, and
- sufficient and appropriate information for management.

This observation is supported by many reports we have published over my years with the Office. For this report, we have drawn examples from some of the chapters issued during 2011.

Clarity of purpose. Successful government programs require a long-term vision of what the program is intended to achieve and a strategic plan to guide activities. Where programs or initiatives involve more than one organization—inside or outside the federal government—roles and responsibilities need to be clearly defined.

In our first audit of Canada's Economic Action Plan, we found that decision makers shared a clear sense of the initiative's purpose—to stimulate the Canadian economy by funding projects that were ready to begin and could be completed within two years. To accomplish this, central agencies and departments worked together to achieve timely implementation; billions of dollars were quickly dispersed while considerable attention was paid to safeguarding against risk and ensuring that eligibility criteria were met. (2010 Fall Report, Chapter 1) Our second audit found that the federal organizations we examined knew they had to manage the risks involved in funding close



John Wiersema, FCA Interim Auditor General of Canada

to 6,000 projects within a fixed two-year period. They monitored the risks, tracked progress and spending, and took corrective action as needed. (2011 Fall Report, Chapter 1)

Our June Status Report chapter on programs for First Nations noted that conditions remain significantly poorer on reserves than in other communities, and are even worsening. This is due in part to a long-standing lack of clarity about responsibility for on-reserve services such as drinking water, housing, and education. First Nations, the federal government, and other stakeholders need to find new ways of working together to achieve better results for First Nations communities. (June 2011 Status Report, Chapter 4)

Another Status Report chapter, on National Police Services, highlighted a continuing lack of clarity in the RCMP about which police services it should be providing to provinces and municipalities, at what level, and who should pay for them. These matters remain unresolved despite the fact that it has been providing these services since 1966. The RCMP has continued to struggle with the rising costs of providing national police services, at the expense of its federal policing responsibilities in areas such as organized crime and drug enforcement. (June 2011 Status Report, Chapter 5)

Committed and sustained leadership. The complexity of many government programs can require years of sustained leadership to achieve desired results. This is often difficult to accomplish given the high rates of turnover in senior positions. While the internal audit function is a relatively small part of government activity, our Status Report discussed the progress the government has made in improving it. This was achieved largely because of committed leadership. Across the government, we found stronger senior management support for the role internal audit can play. The Office of the Comptroller General has provided leadership, guidance, and tools to the internal audit community. In addition, independent departmental audit committees have been established whose collective skills and experience enable them to provide deputy heads of departments with objective advice and recommendations. (June 2011 Status Report, Chapter 3)

However, we have often seen government programs or initiatives where stronger leadership is needed to resolve long-standing problems. The chapter in this report on issuing visas provides an example.

The chapter notes some problems that we have identified in our audits of Citizenship and Immigration Canada (CIC) since 2000. For example, tools and guidance available to visa officers are not kept up to date;

screening for danger to public health is still primarily based on the same diseases—syphilis and tuberculosis—as 50 years ago, though today some 56 diseases are reportable in Canada; and many risk indicators, key to identifying potentially inadmissible foreign nationals, have not been reviewed or updated for years. Committed leadership could have ensured long ago that these issues were addressed. At the same time, CIC and the Canada Border Services Agency, who have shared responsibility since 2004 for security aspects of admissibility, are still dealing with problems in their relationship and clarifying how they will work together. (2011 Fall Report, Chapter 2)

In October 2011, the Commissioner of the Environment and Sustainable Development noted that the Government of Canada has committed to addressing climate change by reducing its national greenhouse gas (GHG) emissions in various plans and agreements since 1992. However, national GHG emissions in 2008 were 24 percent higher than in 1990. Further, in its first climate change plan, the government was aiming to reduce emissions by 282 million tonnes; by the 2010 plan, it was aiming to reduce them by only 28 million tonnes. The government needs to establish a target it is committed to achieving, as well as the means of doing so. (October 2011 CESD Report, Chapter 1)

Our Spring 2011 chapter on the Reserve Force Pension Plan found that no one senior official was made responsible for the plan. This resulted in a division of responsibilities and a lack of coordinated leadership. Parliament authorized the creation of this plan in 1999. Eight years later, in 2007, National Defence introduced the plan but was not prepared to operate it. After three years, only 400 of the 9,000 pension buyback applications by reservists had been processed; by 2014 about 3,900 files could still be in the backlog. Many reservists will wait seven years or longer to find out what their pension will be and how much it will cost them. (2011 Spring Report, Chapter 3)

Predictable and stable funding. The business of government is long-term in nature, and many government programs require many years to achieve the desired results. In contrast, the government's funding cycle for non-statutory programs is short-term in its focus. In addition, many ongoing programs depend on time-limited funding that has to be renewed periodically to allow the program to continue.

In our Status Report on programs for First Nations on reserves, we noted the difficulties caused by the lack of an appropriate funding mechanism for services. Funds are appropriated annually and provided through contribution agreements, most of which must be renewed

each year. The funds may not be available until several months into the period to be funded; one reason is that new agreements cannot be finalized until departments have reviewed documentation and confirmed that funds from the previous period were used appropriately. Consequently, First Nations must often reallocate funds from elsewhere to continue meeting community service requirements. This creates uncertainty and instability for those who rely on the services. (June 011 Status Report, Chapter 4)

In the same report, we found that the RCMP has been reallocating funds from other programs and activities to cover the rising costs of providing national police services. To balance its resources without additional funding, the RCMP will have to either reduce these services or sustain them by permanently redirecting funding from other RCMP programs. (June 2011 Status Report, Chapter 5)

Similarly, in 2006, we reported that demands on Health Canada's Medical Devices Program were increasing with the number of devices in the marketplace and the complexity of new technologies and applications. Yet the program's funding remained constant, even decreasing for core activities, and it was becoming more difficult for program managers to fully meet regulatory responsibilities for protection of Canadians' health and safety. This year, our Status Report noted that to help resolve the shortfall, Health Canada has increased funding to the program and updated user fees. (June 2011 Status Report, Chapter 6)

Predictable, stable funding contributes to the ability to manage a program strategically and for the long term, but only if decision makers understand the full long-term costs. Before decisions are made to go forward with an initiative that commits the government to a future course of action involving years or even decades, it is important that decision makers consider all of the costs, not just the start-up costs.

National Defence has pointed to a significant gap between the demand for maintenance and repair services and the funds made available. It also says its long-term investment plan for new equipment has likely allocated insufficient funds for equipment life-cycle costs. The Department has found that the impacts of postponing maintenance and repair work include the need for more expensive corrective repairs, and reduced availability and life expectancy of military equipment. (2011 Fall Report, Chapter 5)

Sufficient and appropriate information for management. Costs are just one type of information that decision makers need. Our audits have found that essential pieces of information needed to manage

the complex and diverse business of government—information on not only costs but also objectives, results, and service levels—are often missing or inadequate.

Federal departments make significant investments in systems that generate huge amounts of information. The government's ability to carry out policies and programs that will serve the needs of Canadians relies on having the right kind of information and then using it to manage well.

Organizations need good financial and other types of information to monitor the delivery of programs and services, exercise stewardship over resources for which they are responsible, support decisions, manage risks, and report on the financial and operating results.

The significant gaps in information needed to understand and respond to the changing state of our environment has been a recurring theme in reports by the Commissioner of the Environment and Sustainable Development. In his October 2011 Report, for example, he notes that insufficient environmental information makes it difficult to understand the combined impacts of oil sands projects in the lower Athabasca region and on ecosystems farther afield. Without knowing the combined effects, decisions about oil sands projects have been based on incomplete, poor, or non-existent environmental information. (October 2011 CESD Report, Chapter 2)

The chapter on issuing visas notes that CIC expects its visa officers to make the best decisions on the admissibility of a visa applicant that they can make in the time and with the information available. Unfortunately, management at CIC and CBSA do not know whether the security and health information provided to visa officers is sound, because there is very little checking on its quality. CBSA has not requested feedback from CIC on the usefulness of the information provided to visa officers, and there is no process to find out how they use the information. About 45 percent of the visa officers we surveyed indicated that one challenge in determining the admissibility of an applicant is the lack of relevant information from security partners. (2011 Fall Report, Chapter 2)

Our Status Report noted that the RCMP's ability to negotiate agreements with provinces and municipalities on the provision of national police services is limited by its lack of adequate information on the cost of providing each service. Accurate cost information is essential to manage its services and resources efficiently. (June 2011 Status Report, Chapter 5)

Our second chapter on the Economic Action Plan notes that job creation was a key objective of one program we looked at, and contribution agreements included specific performance indicators related to job creation. However, job information was collected in a variety of ways and cannot be relied on to assess the program's success in meeting this key objective. In addition, fragmented reporting on the performance of Economic Action Plan programs in departmental performance reports has made it difficult to get a picture of the initiative's overall results. (2011 Fall Report, Chapter 1)

Over the years, we have issued few positive reports on information for management. Instead, we have found that poor information is a widespread, chronic problem in the federal government. We have seen many initiatives that require managers to feed information to the centre, whether to central agencies or to departmental corporate services—the reporting burden that exists in government. In contrast, managers are not systematically collecting and using the information they need to manage their programs, and they are not held accountable for this.

Conclusion

The government will need to make significant investments to upgrade information systems and aging infrastructure, among others. This will require careful long-range planning, predictable and stable funding, and good information as well as good use of that information. In addition, committed and sustained leadership and clarity are needed as to the roles and responsibilities of public officials charged with managing the complex and challenging issues that the government is facing.

These matters are important and timely in light of the government's current strategic review. Carrying out the review will be challenging for programs that lack one or more of these essential elements. I encourage the government to ensure that programs continuing after completion of the review have these elements in place. I also encourage the government to ensure that managers have the necessary tools, people, and information systems to achieve government priorities. While they must be left to manage, it will be important that managers be held to account for results achieved.

Main Points—Chapters 1 to 5





Canada's Economic Action Plan

Chapter 1

Main Points

What we examined

In January 2009, the Government of Canada launched its Economic Action Plan to stimulate the economy in response to the global economic downturn. This stimulus plan represented about \$47 billion in federal spending and an additional \$14 billion funded by provinces and territories. Its purpose was to create jobs, build infrastructure, accelerate housing construction, stimulate spending by Canadians, and support businesses and communities. Budget 2009 also contained measures to add stability to the financial sector, which sought to improve access to financing for consumers and business by providing up to \$200 billion in credit.

Our first audit of the Economic Action Plan, reported in October 2010, examined program design and delivery mechanisms put in place by selected federal departments and agencies to implement the Economic Action Plan.

Our second audit of the Economic Action Plan is the subject of this chapter. The audit looked at three programs with a total dollar value of \$7 billion. The \$4 billion Infrastructure Stimulus Fund targeted provincial, territorial, and municipal construction-ready projects to build or rehabilitate infrastructure. The \$2 billion Knowledge Infrastructure Program targeted post-secondary institutions across Canada for new construction, deferred maintenance, repair, and expansion of projects to improve the quality of research and development and deliver advanced knowledge and skills training. The \$1 billion Community Adjustment Fund was established to create or maintain jobs and support businesses in communities hit hard by the economic downturn.

Our audit included two departments and five regional development agencies that distributed funds under the programs. We examined whether they had monitored and reported on program spending and results.

During our audit, the government extended the completion deadline for many projects from 31 March 2011 to 31 October 2011. This chapter is a report on selected programs up to 31 March 2011, the date when our audit work was substantially completed. It is not a report on the final results of the Economic Action Plan.

Why it's important

Given the short time frame planned for the Economic Action Plan, as well as the large amounts of public money involved, it was important that the government mitigate risks through appropriate monitoring of programs at every stage, timely tracking and reporting of costs, adherence to its own Policy on Transfer Payments, and reliable reporting of results.

A key risk for the government was that its measures would fail to quickly stimulate the Canadian economy. That was the reason for giving priority to projects that were "construction ready" and requiring that projects be completed by 31 March 2011, to support the government's assertion that stimulus measures would be targeted, timely, and temporary.

What we found

- For the three Economic Action Plan programs we audited, the federal government monitored the progress and spending of projects, permitting it to take corrective action in a number of cases. Progress on many projects was slower than initially expected. Departments and agencies delivering the three programs that we audited reported that 4,070 out of 5,845 projects (70 percent) were completed by the 31 March 2011 deadline. Following the federal government's announcement of a deadline extension, almost one third of projects in the two largest programs we examined were granted an extension to 31 October 2011. The decision to extend the time frames of these programs was supported by an analysis conducted by the Privy Council Office and the Department of Finance Canada.
- Spending figures provided by the departments and agencies as
 of 31 March 2011 indicate that the three programs had largely
 achieved the Economic Action Plan objective to spend federal
 resources within a two-year time frame. However, total federal
 spending for all three programs will not be known until projects
 submit final claims and close-out reports to the federal entities.
- Although a key objective of the Community Adjustment Fund was
 to create and maintain jobs in communities hit hard by the economic
 downturn, the design of the program did not allow for performance
 measurement and reporting against this key objective.

• Infrastructure Canada, Industry Canada, and the regional development agencies reported performance information on their Economic Action Plan programs in various places throughout their departmental performance reports. In our view, this fragmented presentation makes it difficult for parliamentarians and Canadians to obtain an overall picture of results achieved against planned performance expectations and public resources spent.

The entities have responded. The entities agree with our recommendations. Their detailed responses follow each recommendation throughout the chapter.



Issuing Visas

Chapter 2

Main Points

What we examined

People from other countries—foreign nationals—who want to enter Canada as permanent residents must obtain a Canadian visa. Foreign nationals who want to enter Canada on a temporary basis must also apply for a visa, unless they are from a visa-exempt country. To obtain a visa, foreign nationals must meet all requirements for the category under which they are applying and must be deemed to be admissible. In 2010, 1.36 million visas (including 317,000 permanent resident visas) were processed at Canadian missions in foreign countries.

Admissibility of foreign nationals into Canada falls under the *Immigration and Refugee Protection Act*. The Act defines various situations where a foreign national would be inadmissible—for example, if the individual presents a risk to the health, safety, or security of Canadians. Administering the various provisions of the Act is a shared responsibility between Citizenship and Immigration Canada (CIC) and the Canada Border Services Agency (CBSA).

Before issuing a visa, CIC officials must determine that the applicant is admissible to Canada. They are supported in making this determination by the CBSA, which—with the help of the Canadian Security Intelligence Service (CSIS) and the Royal Canadian Mounted Police (RCMP)—coordinates and provides intelligence information related to the applicants.

We examined whether Citizenship and Immigration Canada and the Canada Border Services Agency have managed the risks associated with determining admissibility before issuing a visa, in line with the objective of the Act to protect the health, safety, and security of Canadians.

Audit work for this chapter was substantially completed on 29 April 2011.

Why it's important

Global events in the last decade have changed the nature of threats to Canadian society. Diseases prevalent in other countries that can be transmitted rapidly worldwide, incidents of terrorism, and organized crime around the world have shown the importance of identifying individuals who present a risk and preventing their entry into Canada.

Identifying visa applicants who are inadmissible to Canada is a highly complex process that relies heavily on the judgment and experience of CIC's visa officers in missions overseas and on the information made available to them. Visa officers are expected to make the best decisions they can with that information in the time they have available. It is critical that visa officers receive from their security and medical partners timely and reliable information on applicants.

What we found

- Citizenship and Immigration Canada and the Canada Border Services Agency have taken some measures to address long-standing weaknesses in the process of determining whether visa applicants are admissible to Canada. However, deficiencies still exist in the measures used to identify foreign nationals who may be inadmissible for health, safety, or security concerns. CIC and the CBSA lack the necessary tools and information to provide assurance that risks related to the admissibility determination process are properly managed.
- Some of the tools and risk indicators that visa officers use to identify inadmissible persons, and to know when to seek advice from security partners, are not kept up to date, nor are they always available.
 Furthermore, many CBSA analysts who provide security advice to visa officers have not received the necessary formal training to do so.
 Documentation to support the advice sent to visa officers offered little insight into how the analysts made their assessments, and in many cases not all the checks that should have been done were completed.
- CIC lacks guidance on the use of two key criteria used in medical screening—danger to public health and danger to public safety—although it has undertaken some work to explain what they mean. Medical screening to determine danger to public health has focused mainly on the same two diseases for the past 50 years—syphilis and tuberculosis. Although today 56 diseases require national surveillance in Canada, CIC has not reviewed whether foreign nationals should also be subject to mandatory testing for some of these diseases.

• CIC and the CBSA do not have systematic quality assurance practices or performance measures in place to know how well they are identifying individuals who are inadmissible because of health, safety, or security concerns. Most quality assurance practices that do exist focus on supporting decisions to refuse a visa. Because those decisions represent a very small percentage of applications each year, this means that the quality of decisions on the vast majority of applications is not reviewed.

The entities have responded. The entities agree with all of our recommendations. Their detailed responses follow the recommendations throughout the chapter.



Payments to Producers— Agriculture and Agri-Food Canada

Chapter 3 M

Main Points

What we examined

Agriculture and Agri-Food Canada (AAFC) has a mandate to provide information, research and technology, and policies and programs to achieve an environmentally sustainable, innovative, and competitive agriculture sector. The Department's work includes supporting productivity and trade, stabilizing farm incomes, and conducting research. The federal government and the provinces and territories share responsibility for stabilizing farm incomes. Since 2008, they have done so through a joint federal/provincial/territorial agreement called the Growing Forward Framework Agreement.

The Department's programs have played an important role in supporting producers' incomes when market income has dropped. Our audit looked at two programs under Growing Forward that, like the Canadian Agricultural Income Stabilization (CAIS) program they replaced, are aimed at protecting agricultural producers from drops in income. AgriInvest is built around savings accounts, with producers' deposits matched by government contributions; AgriStability is a far more complex program designed to protect against larger drops in income. Costs of the two programs total \$1 billion annually, funded 60 percent by the federal government and 40 percent by provinces. About 88 percent of payments under the AgriStability program are now delivered by the provinces.

We also looked at the \$284 million Tobacco Transition Program, aimed at replacing the quota system, helping tobacco producers move out of the tobacco industry, and improving the viability of those who remain.

We looked at how the programs were developed, implemented, and administered. In particular, we looked at the quality of the risk assessment process and the process for continuous improvement. We also looked at the design and monitoring of funding and program delivery agreements between the Department and the provinces and territories or delivery organizations. We did not audit the provincial agencies or third-party organizations that participated in the delivery of programs.

Audit work for this chapter was substantially completed on 2 May 2011.

Why it's important

The Canadian agriculture and agri-food industry is vital to Canada's economic success and its food supply. It encompasses several industries, including primary agriculture, input suppliers, food and beverage processing and distribution, and wholesale and retail food industries. According to the Department, this industry accounted for 8.2 percent of total gross domestic product in 2009.

The agricultural sector faces several challenges, including increasing international competition, rapid technological improvements, increased importance of environmental and health concerns, increasing input costs, rapidly evolving consumer preferences, changes in foreign exchange, and more volatility due to weather changes and disease.

What we found

- To improve the design of its producer income support programs, Agriculture and Agri-Food Canada carried out industry consultation, a strategic review, producer surveys, and focus groups. Working with provinces and territories, the Department has made progress on some design issues, but long-standing concerns with AgriStability remain—clarity of program objectives, timely access to program funding, and program complexity that affects producers' ability to reasonably predict payment amounts.
- The Department has made progress in addressing program administration issues raised in our 2007 audit—for example, payment accuracy and management of underpayments to producers. However, it has not systematically followed up on causes of delays in payments to producers in order to accelerate payments. Despite improvement, the Department has not yet met its AgriStability processing time targets, and producers can wait up to two years after an income loss to receive a payment. In addition, the Department has not collected information on processing times for AgriInvest.
- Although federal/provincial/territorial accountabilities for performance reporting were not specified in the Growing Forward Framework Agreement, a performance measurement framework has since been agreed to by all governments. When fully implemented, overall national performance against service standards will be reported to Parliament and the public. With regard to assessing provincial capacity for AgriStability administration and transferring it to the provinces of British Columbia and Saskatchewan in 2010, the Department followed a sound process.
- The Department had to develop the Tobacco Transition Program
 within a short time frame and did not first conduct a thorough risk
 analysis. The agreement implementing the program did not provide
 clear terms and conditions to ensure that recipients would not enter

into business arrangements that would undermine the intent of the program. In addition, a number of times the Department changed its interpretation of what was and was not allowed under the Agreement, resulting in confusion for producers. As a result, the Department was successful in controlling some, but not all, business arrangements that it believed would undermine the intent of the program.

The Department has responded. The Department agrees with all of our recommendations. Its responses follow each recommendation throughout the chapter.



Regulating Pharmaceutical Drugs— Health Canada

Chapter 4 Ma

Main Points

What we examined

Pharmaceutical drugs are mostly synthetic products made from chemicals. They are meant to improve the health and well-being of patients by helping to prevent and treat disease, reduce pain and suffering, and extend and save lives. Some higher-risk drugs, such as those used to treat diseases, require a prescription from a physician. Other lower-risk drugs, such as cough syrup and antacids, are sold without a prescription and are readily available to the public.

Health Canada, through the *Food and Drugs Act*, regulates the safety, efficacy, and quality of all pharmaceutical drugs for use by humans in Canada before and after the products enter the Canadian marketplace. The Department does this through a combination of scientific review, monitoring, compliance, and enforcement activities. It aims to ensure that the public has timely access to safe and effective pharmaceutical drugs and that those who need to know of safety concerns are informed.

We examined how Health Canada regulates clinical trials of new pharmaceutical drugs and reviews submissions seeking approval of new drugs for sale in Canada or of changes to drugs already on the market. We also examined how the Department monitors product safety and ensures that potential safety concerns are communicated to health care professionals and the public. In addition, we looked at how Health Canada enforces industry compliance with regulatory requirements governing the testing, production, and sale of drugs. We did not examine the soundness of the Department's regulatory decisions or the safety or efficacy of drugs.

The period under audit for this chapter was 1 January 2009 to 31 December 2010. Audit work for this chapter was substantially completed on 31 May 2011.

Why it's important

There are about 13,000 prescription and non-prescription drugs on the Canadian market. Pharmaceutical drugs play an important role in Canada's health care system and economy. In 2008, the Canadian retail market for prescription and over-the-counter drugs was valued at about \$28 billion, with prescription drug purchases accounting for almost 84 percent of total retail drug expenditures. According to IMS Brogan, a well-recognized provider of data to Health Canada and the pharmaceutical industry, about 505 million prescriptions were dispensed by Canadian retail pharmacies in 2010.

With an aging population, the role of pharmaceutical drugs is expected to grow as researchers come up with new drug therapies to replace earlier treatments or provide new options where no treatment existed before. Canadians who purchase and consume pharmaceuticals authorized for sale in Canada rely on the government and industry to monitor the safety of these products. Health Canada has a responsibility to help protect the public against undue health and safety risks from the use of pharmaceutical drugs.

What we found

- The Department does not take timely action in its regulatory activities, with the exception of its review of two types of drug submissions. In particular, the Department is slow to assess potential safety issues. It can take more than two years to complete an assessment of potential safety issues and to provide Canadians with new safety information.
- The Department received 4,400 drug submissions in 2009 and 2010.
 It has put in place processes and procedures to ensure that its drug reviews are consistent and high quality. However, it has not assessed whether these processes and procedures have been consistently interpreted and applied across its four review bureaus.
- Health Canada does not disclose information on drug submissions
 that it has rejected or information on the status of the drugs it has
 approved with conditions. In addition, the Department has not
 acted on its long-standing commitment to disclose more information
 about clinical trials it has authorized. This increases the risk that
 Canadians may be unaware of new treatment options or may
 unknowingly participate in an unauthorized trial.
- Health Canada's conflict-of-interest guidelines and Code of Conduct are consistent with government policy on conflict of interest.
 However, unlike another major regulator of pharmaceutical drugs and some federal departments that have developed conflict-of-interest requirements for specific work assignments, the Department has not determined what measures are necessary for its review activities.

The Department has responded. The Department agrees with all of our recommendations. Its detailed responses follow the recommendations throughout the chapter.



Maintaining and Repairing Military Equipment—National Defence

Chapter 5 Main Points

What we examined

National Defence and the Canadian Forces own, operate, and are responsible for maintaining and repairing military aircraft, ships, and land vehicles costing more than \$30 billion. In 2009–10, National Defence spent more than \$2 billion to maintain and repair its military equipment. This included expenses for routine inspections, preventive maintenance, corrective repairs, spare parts supply, periodic repair and overhaul, engineering changes, and other related tasks.

Thousands of personnel are engaged in maintenance and repair activities, which include everything from turning wrenches on bases or while deployed on missions to engineering, logistics and spare parts management, training, contracting, and administrative support.

We examined how National Defence allocates and manages financial resources for the maintenance and repair of its military equipment. We also examined its approaches to contracting for maintenance and repair services.

Audit work for this chapter was substantially completed on 30 April 2011.

Why it's important

To undertake training and to meet assigned missions safely and successfully, military equipment must be kept in good working condition and be ready for action on short notice. How National Defence allocates the funds available—and the reliability of the information it uses to support short- and long-term decisions—is critical to the ability and readiness of the Canadian Forces to meet their assigned missions.

Military spending on maintenance and repair also makes a significant contribution to the Canadian economy every year. Many Canadian companies depend on it for a portion of their business. According to the 2008 *Canada First* Defence Strategy, the government plans to spend \$60 billion on new military equipment over 20 years and \$140 billion for spare parts, maintenance, and training.

Over the last decade, National Defence has made sweeping changes in its approach to contracting for maintenance and repair of both existing and new equipment. The changes transfer much of the responsibility to the private sector, with significant implications for National Defence and Canada's defence industry. The new contracting approach for existing equipment was intended to reduce the Department's contract management activities and costs by bundling hundreds of short-term maintenance contracts into a few longer-term contracts. The approach for new equipment goes even further, awarding both the acquisition and the long-term maintenance and repair contracts to the original equipment manufacturer or supplier. The Department has identified significant risks in this approach, including limited flexibility if requirements change over the life of the equipment, dwindling maintenance and repair skills and expertise in the Canadian Forces, and total dependence on one supplier for each fleet.

What we found

- Overall, National Defence has planned and managed the maintenance and repair of military equipment to meet operational priorities in the short term. The annual process of allocating available funds provides an effective forum to discuss priorities, with wide participation of those responsible for maintaining and repairing military equipment and those who need it for operations and training.
- National Defence's ability to meet training and operational requirements over the long term is at risk due to weaknesses in implementation and oversight of its contracting approaches for maintenance and repair, deficient management information systems, and the lack of sufficient cost and performance information.
- The Department has not taken the actions or provided the central resources and oversight required to support the implementation of its new contracting approaches successfully. The lack of concerted action and follow-through on the new contracting approach for existing military equipment has resulted in slower and more limited implementation than planned. As a consequence, National Defence has lost opportunities to derive the potential benefits of improved performance, improved accountability, and reduced costs. In addition, National Defence is not adequately monitoring and mitigating the significant risks created by its approach for new equipment.
- There are long-standing deficiencies in information management systems used to support decision-making for maintenance and repair activities, first raised by us in a 2001 audit. As a result, National Defence lacks complete, reliable, and integrated

information on the total actual costs of maintenance and repair, because some of the costs—salaries and infrastructure, for example—are not captured in its asset management information systems. The absence of this information impedes its ability to make informed decisions about the life-cycle management of its fleets or to determine whether it is putting enough funds each year into maintenance and repair. In 2001, National Defence expected to fully implement an integrated asset management system by 2004. The Department now expects a new system to be introduced on all Canadian Forces bases by mid-2012. Fully implementing this new system will likely take many years.

• There is a significant gap between the demand for maintenance and repair services and the funds made available. In addition, National Defence has indicated it is likely that its long-term investment plan for new equipment has allocated insufficient funds for equipment life-cycle costs. Although National Defence knows that postponing maintenance and repair tasks creates future risks—such as reduced availability of equipment, more laborious and expensive repairs, and reduced life expectancy of military equipment—the Department does not regularly monitor these impacts. Consequently, it does not know the specific long-term impacts of the funding gap on operations and training activities.

The Department has responded. The Department agrees with all of our recommendations. Its detailed responses follow the recommendations throughout the chapter.

Appendices



Appendix A Auditor General Act

An Act respecting the office of the Auditor General of Canada and sustainable development monitoring and reporting

Short Title

Short title

1. This Act may be cited as the Auditor General Act.

Interpretation

Definitions

2. In this Act,

"appropriate Minister"

"appropriate Minister" has the meaning assigned by section 2 of the Financial Administration Act:

"Auditor General"

"Auditor General" means the Auditor General of Canada appointed pursuant to subsection 3(1);

"category I department"

"category I department" means

- (a) any department named in schedule I to the Financial Administration Act,
- (b) any department in respect of which a direction has been made under subsection 11(3) of the Federal Sustainable Development Act; and
- (c) any agency set out in the schedule to the Federal Sustainable Development Act.

"Commissioner"

"Commissioner" means the Commissioner of the Environment and Sustainable Development appointed under subsection 15.1(1);

"Crown corporation"

"Crown corporation" has the meaning assigned to that expression by section 83 of the Financial Administration Act;

"department"

"department" has the meaning assigned to that term by section 2 of the Financial Administration Act;

"funding agreement"

"funding agreement" has the meaning given to that expression by subsection

42(4) of the Financial Administration Act;

"recipient"

"recipient" has the meaning given to that expression by subsection 42(4) of the

Financial Administration Act;

"registrar"

"registrar" means the Bank of Canada and a registrar appointed under Part IV of

the Financial Administration Act;

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"sustainable development"

"sustainable development" means development that meets the needs of the present without compromising the ability of future generations to meet their own needs;

Control

- **2.1** (1) For the purpose of paragraph (d) of the definition "recipient" in subsection 42(4) of the *Financial Administration Act*, a municipality or government controls a corporation with share capital if
 - (a) shares of the corporation to which are attached more than fifty per cent of the votes that may be cast to elect directors of the corporation are held, otherwise than by way of security only, by, on behalf of or in trust for that municipality or government; and
 - (b) the votes attached to those shares are sufficient, if exercised, to elect a majority of the directors of the corporation.

Control

(2) For the purpose of paragraph (d) of the definition "recipient" in subsection 42(4) of the *Financial Administration Act*, a corporation without share capital is controlled by a municipality or government if it is able to appoint the majority of the directors of the corporation, whether or not it does so.

Auditor General of Canada

Appointment

3. (1) The Governor in Council shall, by commission under the Great Seal, appoint an Auditor General of Canada after consultation with the leader of every recognized party in the Senate and House of Commons and approval of the appointment by resolution of the Senate and House of Commons.

Tenure

- (1.1) The Auditor General holds office during good behaviour for a term of 10 years but may be removed for cause by the Governor in Council on address of the Senate and House of Commons.
 - (2) [Repealed, 2011, c. 15, s. 17]

Re-appointment

(3) Once having served as the Auditor General, a person is not eligible for re-appointment to that office.

Interim appointment

(4) In the event of the absence or incapacity of the Auditor General or if that office is vacant, the Governor in Council may appoint any qualified auditor to hold that office in the interim for a term not exceeding six months, and that person shall, while holding office, be paid the salary or other remuneration and expenses that may be fixed by the Governor in Council.

Salary

Pension benefits

4. (1) The Auditor General shall be paid a salary equal to the salary of a puisne judge of the Supreme Court of Canada.

(2) The provisions of the *Public Service Superannuation Act*, other than those relating to tenure of office, apply to the Auditor General except that a person appointed as Auditor General from outside the public service may, by notice in writing given to the President of the Treasury Board not more than sixty days after the date of his appointment as Auditor General, elect to participate in the pension plan provided for in the *Diplomatic Service (Special) Superannuation Act* in which case the provisions of that Act, other than those relating to tenure of office, apply to him and the provisions of the *Public Service Superannuation Act* do not apply to him.

Powers and Duties

Examination

5. The Auditor General is the auditor of the accounts of Canada, including those relating to the Consolidated Revenue Fund and as such shall make such examinations and inquiries as he considers necessary to enable him to report as required by this Act.

Idem

6. The Auditor General shall examine the several financial statements required by section 64 of the *Financial Administration Act* to be included in the Public Accounts, and any other statement that the President of the Treasury Board or the Minister of Finance may present for audit and shall express his opinion as to whether they present fairly information in accordance with stated accounting policies of the federal government and on a basis consistent with that of the preceding year together with any reservations he may have.

Annual and additional reports to the House of Commons

- 7. (1) The Auditor General shall report annually to the House of Commons and may make, in addition to any special report made under subsection S(1) or 19(2) and the Commissioner's report under subsection 23(2), not more than three additional reports in any year to the House of Commons
 - (a) on the work of his office; and,
 - (b) on whether, in carrying on the work of his office, he received all the information and explanations he required.

Idem

- (2) Each report of the Auditor General under subsection (1) shall call attention to anything that he considers to be of significance and of a nature that should be brought to the attention of the House of Commons, including any cases in which he has observed that
 - (a) accounts have not been faithfully and properly maintained or public money has not been fully accounted for or paid, where so required by law, into the Consolidated Revenue Fund;
 - (b) essential records have not been maintained or the rules and procedures applied have been insufficient to safeguard and control public property, to secure an effective check on the assessment, collection and proper allocation of the revenue and to ensure that expenditures have been made only as authorized;
 - (c) money has been expended other than for purposes for which it was appropriated by Parliament;
 - (d) money has been expended without due regard to economy or efficiency;
 - (e) satisfactory procedures have not been established to measure and report the effectiveness of programs, where such procedures could appropriately and reasonably be implemented; or
 - (f) money has been expended without due regard to the environmental effects of those expenditures in the context of sustainable development.

Submission of annual report to Speaker and tabling in the House of Commons

(3) Each annual report by the Auditor General to the House of Commons shall be submitted to the Speaker of the House of Commons on or before December 31 in the year to which the report relates and the Speaker of the House of Commons shall lay each such report before the House of Commons forthwith after receiving it or, if that House is not then sitting, on any of the first fifteen days on which that House is sitting after the Speaker receives it.

Notice of additional reports to Speaker and tabling in the House of Commons (4) Where the Auditor General proposes to make an additional report under subsection (1), the Auditor General shall send written notice to the Speaker of the House of Commons of the subject-matter of the proposed report.

Submission of additional reports to Speaker and tabling in the House of Commons

(5) Each additional report of the Auditor General to the House of Commons made under subsection (1) shall be submitted to the House of Commons on the expiration of thirty days after the notice is sent pursuant to subsection (4) or any longer period that is specified in the notice and the Speaker of the House of Commons shall lay each such report before the House of Commons forthwith after receiving it or, if that House is not then sitting, on any of the first fifteen days on which that House is sitting after the Speaker receives it.

Inquiry and report

- 7.1 (1) The Auditor General may, with respect to a recipient under any funding agreement, inquire into whether
 - (a) the recipient has failed to fulfil its obligations under any funding agreement;
 - (b) money the recipient has received under any funding agreement has been used without due regard to economy and efficiency;
 - (c) the recipient has failed to establish satisfactory procedures to measure and report on the effectiveness of its activities in relation to the objectives for which it received funding under any funding agreement;
 - (d) the recipient has failed to faithfully and properly maintain accounts and essential records in relation to any amount it has received under any funding agreement; or
 - (e) money the recipient has received under any funding agreement has been expended without due regard to the environmental effects of those expenditures in the context of sustainable development.

Report

(2) The Auditor General may set out his or her conclusions in respect of an inquiry into any matter referred to in subsection (1) in the annual report, or in any of the three additional reports, referred to in subsection 7(1). The Auditor General may also set out in that report anything emerging from the inquiry that he or she considers to be of significance and of a nature that should be brought to the attention of the House of Commons.

Special report to the House of Commons

8. (1) The Auditor General may make a special report to the House of Commons on any matter of pressing importance or urgency that, in the opinion of the Auditor General, should not be deferred until the presentation of the next report under subsection 7(1).

Submission of reports to Speaker and tabling in the House of Commons

(2) Each special report of the Auditor General to the House of Commons made under subsection (1) or 19(2) shall be submitted to the Speaker of the House of Commons and shall be laid before the House of Commons by the Speaker of the House of Commons forthwith after receipt thereof by him, or if that House is not then sitting, on the first day next thereafter that the House of Commons is sitting.

Idem

9. The Auditor General shall

- (a) make such examination of the accounts and records of each registrar as he deems necessary, and such other examinations of a registrar's transactions as the Minister of Finance may require, and
- (b) when and to the extent required by the Minister of Finance, participate in the destruction of any redeemed or cancelled securities or unissued reserves of securities authorized to be destroyed under the *Financial Administration Act*,

and he may, by arrangement with a registrar, maintain custody and control, jointly with that registrar, of cancelled and unissued securities.

Improper retention of public money

10. Whenever it appears to the Auditor General that any public money has been improperly retained by any person, he shall forthwith report the circumstances of the case to the President of the Treasury Board.

Inquiry and report

11. The Auditor General may, if in his opinion such an assignment does not interfere with his primary responsibilities, whenever the Governor in Council so requests, inquire into and report on any matter relating to the financial affairs of Canada or to public property or inquire into and report on any person or organization that has received financial aid from the Government of Canada or in respect of which financial aid from the Government of Canada is sought.

Advisory powers

12. The Auditor General may advise appropriate officers and employees in the federal public administration of matters discovered in his examinations and, in particular, may draw any such matter to the attention of officers and employees engaged in the conduct of the business of the Treasury Board.

Access to Information

Access to information

13. (1) Except as provided by any other Act of Parliament that expressly refers to this subsection, the Auditor General is entitled to free access at all convenient times to information that relates to the fulfilment of his or her responsibilities and he or she is also entitled to require and receive from members of the federal public administration any information, reports and explanations that he or she considers necessary for that purpose.

Stationing of officers in departments

(2) In order to carry out his duties more effectively, the Auditor General may station in any department any person employed in his office, and the department shall provide the necessary office accommodation for any person so stationed.

Oath of secrecy

(3) The Auditor General shall require every person employed in his office who is to examine the accounts of a department or of a Crown corporation pursuant to this Act to comply with any security requirements applicable to, and to take any oath of secrecy required to be taken by, persons employed in that department or Crown corporation.

Inquiries

(4) The Auditor General may examine any person on oath on any matter pertaining to any account subject to audit by him and for the purposes of any such examination the Auditor General may exercise all the powers of a commissioner under Part I of the *Inquiries Act*.

Reliance on audit reports of Crown corporations

14. (1) Notwithstanding subsections (2) and (3), in order to fulfil his responsibilities as the auditor of the accounts of Canada, the Auditor General may rely on the report of the duly appointed auditor of a Crown corporation or of any subsidiary of a Crown corporation.

Auditor General may request information

(2) The Auditor General may request a Crown corporation to obtain and furnish him with such information and explanations from its present or former directors, officers, employees, agents and auditors or those of any of its subsidiaries as are, in his opinion, necessary to enable him to fulfil his responsibilities as the auditor of the accounts of Canada.

Direction of the Governor in Council

(3) If, in the opinion of the Auditor General, a Crown corporation, in response to a request made under subsection (2), fails to provide any or sufficient information or explanations, he may so advise the Governor in Council, who may thereupon direct the officers of the corporation to furnish the Auditor General with such information and explanations and to give him access to those records, documents, books, accounts and vouchers of the corporation or any of its subsidiaries access to which is, in the opinion of the Auditor General, necessary for him to fulfil his responsibilities as the auditor of the accounts of Canada.

Staff of the Auditor General

Officers, etc.

15. (1) The officers and employees that are necessary to enable the Auditor General to perform his or her duties are to be appointed in accordance with the *Public Service Employment Act* and, subject to subsections (2) to (5), the provisions of that Act apply to those officers and employees.

Public Service Employment Act —employer and deputy head

(2) The Auditor General may exercise the powers and perform the functions of the employer and deputy head under the *Public Service Employment Act* within the meaning of those terms in subsection 2(1) of that Act.

Public Service Employment Act —Commission (3) The Auditor General may, in the manner and subject to the terms and conditions that the Public Service Commission directs, exercise the powers and perform the functions of that Commission under the *Public Service Employment* Act, other than its powers and functions in relation to the hearing of allegations by a candidate under sections 118 and 119 of that Act and its power to make regulations.

Delegation

(4) The Auditor General may authorize any person employed in his or her office to exercise and perform, in any manner and subject to any terms and conditions that he or she directs, any of his or her powers and functions under subsections (2) and (3).

Sub-delegation

(5) Any person authorized under subsection (4) may, subject to and in accordance with the authorization, authorize one or more persons under that person's jurisdiction to exercise any power or perform any function to which the authorization relates.

Appointment of Commissioner

15.1 (1) The Auditor General shall, in accordance with the *Public Service Employment Act*, appoint a senior officer to be called the Commissioner of the Environment and Sustainable Development who shall report directly to the Auditor General.

Commissioner's duties

(2) The Commissioner shall assist the Auditor General in performing the duties of the Auditor General set out in this Act that relate to the environment and sustainable development.

Responsibility for human resources management

16. The Auditor General is authorized, in respect of persons appointed in his or her office, to exercise the powers and perform the functions of the Treasury Board that relate to human resources management within the meaning of paragraph 7(1)(e) and section 11.1 of the *Financial Administration Act*, as well as those of deputy heads under subsection 12(2) of that Act, as that subsection reads without regard to any terms and conditions that the Governor in Council may direct, including the determination of terms and conditions of employment and the responsibility for employer and employee relations.

Delegation

16.1 (1) The Auditor General may authorize any person employed in his or her office to exercise and perform, in any manner and subject to any terms and conditions that he or she directs, any of his or her powers and functions in relation to human resources management.

Sub-delegation

(2) Any person authorized under subsection (1) may, subject to and in accordance with the authorization, authorize one or more persons under that person's jurisdiction to exercise any power or perform any function to which the authorization relates.

Contract for professional services

16.2 Subject to any other Act of Parliament or regulations made under any Act of Parliament, but without the approval of the Treasury Board, the Auditor General may, within the total dollar limitations established for his or her office in appropriation Acts, contract for professional services.

Classification standards

17. Classification standards may be prepared for persons employed in the office of the Auditor General to conform with the classifications that the Auditor General recognizes for the purposes of that office.

Delegation

18. The Auditor General may designate a senior member of his staff to sign on his behalf any opinion that he is required to give and any report, other than his annual report on the financial statements of Canada made pursuant to section 64 of the *Financial Administration Act* and his reports to the House of Commons under this Act, and any member so signing an opinion or report shall indicate beneath his signature his position in the office of the Auditor General and the fact that he is signing on behalf of the Auditor General.

Immunities

Immunity as witness

18.1 The Auditor General, or any person acting on behalf or under the direction of the Auditor General, is not a competent or compellable witness — in respect of any matter coming to the knowledge of the Auditor General or that person as a result of performing audit powers, duties or functions under this or any other Act of Parliament during an examination or inquiry — in any proceedings other than a prosecution for an offence under section 131 of the *Criminal Code* (perjury) in respect of a statement made under this Act.

Protection from prosecution

18.2 (1) No criminal or civil proceedings lie against the Auditor General, or against any person acting on behalf or under the direction of the Auditor General, for anything done, reported or said in good faith in the course of the performance or purported performance of audit powers, duties or functions under this or any other Act of Parliament.

Defamation

- (2) For the purposes of any law relating to defamation,
 - (a) anything said, any information supplied or any document or thing produced in good faith by or on behalf of the Auditor General, in the course of the performance or purported performance of audit powers, duties or functions under this or any other Act of Parliament, is privileged; and
 - (b) any report made in good faith by the Auditor General in the course of the performance or purported performance of audit powers, duties or functions under this or any other Act of Parliament, and any fair and accurate account of the report made in good faith in a newspaper or any other periodical publication or in a broadcast, is privileged.

Estimates

Estimates

19. (1) The Auditor General shall annually prepare an estimate of the sums that will be required to be provided by Parliament for the payment of the salaries, allowances and expenses of his office during the next ensuing fiscal year.

Special report

(2) The Auditor General may make a special report to the House of Commons in the event that amounts provided for his office in the estimates submitted to Parliament are, in his opinion, inadequate to enable him to fulfil the responsibilities of his office.

Appropriation allotments

20. The provisions of the *Financial Administration Act* with respect to the division of appropriations into allotments do not apply in respect of appropriations for the office of the Auditor General.

Audit of the Office of the Auditor General

Audit of the office of the Auditor General

21. (1) A qualified auditor nominated by the Treasury Board shall examine the receipts and disbursements of the office of the Auditor General and shall report annually the outcome of his examinations to the House of Commons.

Submission of reports and tabling

(2) Each report referred to in subsection (1) shall be submitted to the President of the Treasury Board on or before the 31st day of December in the year to which the report relates and the President of the Treasury Board shall lay each such report before the House of Commons within fifteen days after receipt thereof by him or, if that House is not then sitting, on any of the first fifteen days next thereafter that the House of Commons is sitting.

Sustainable Development

Purpose

- 21.1 In addition to carrying out the functions referred to in subsection 23(3), the purpose of the Commissioner is to provide sustainable development monitoring and reporting on the progress of category I departments towards sustainable development, which is a continually evolving concept based on the integration of social, economic and environmental concerns, and which may be achieved by, among other things,
 - (a) the integration of the environment and the economy;
 - (b) protecting the health of Canadians;
 - (c) protecting ecosystems;
 - (d) meeting international obligations;
 - (e) promoting equity;
 - (f) an integrated approach to planning and making decisions that takes into account the environmental and natural resource costs of different economic options and the economic costs of different environmental and natural resource options;

- (g) preventing pollution; and
- (h) respect for nature and the needs of future generations.

Petitions received

22. (1) Where the Auditor General receives a petition in writing from a resident of Canada about an environmental matter in the context of sustainable development that is the responsibility of a category I department, the Auditor General shall make a record of the petition and forward the petition within fifteen days after the day on which it is received to the appropriate Minister for the department.

Acknowledgement to be sent

(2) Within fifteen days after the day on which the Minister receives the petition from the Auditor General, the Minister shall send to the person who made the petition an acknowledgement of receipt of the petition and shall send a copy of the acknowledgement to the Auditor General.

Minister to respond

(3) The Minister shall consider the petition and send to the person who made it a reply that responds to it, and shall send a copy of the reply to the Auditor General, within

- (a) one hundred and twenty days after the day on which the Minister receives the petition from the Auditor General; or
- (b) any longer time, where the Minister personally, within those one hundred and twenty days, notifies the person who made the petition that it is not possible to reply within those one hundred and twenty days and sends a copy of that notification to the Auditor General.

Multiple petitioners

(4) Where the petition is from more than one person, it is sufficient for the Minister to send the acknowledgement and reply, and the notification, if any, to one or more of the petitioners rather than to all of them.

Duty to monitor

- 23. (1) The Commissioner shall make any examinations and inquiries that the Commissioner considers necessary in order to monitor
 - (a) the extent to which category I departments have contributed to meeting the targets set out in the Federal Sustainable Development Strategy and have met the objectives, and implemented the plans, set out in their own sustainable development strategies laid before the Houses of Parliament under section 11 of the Federal Sustainable Development Act; and
 - (b) the replies by Ministers required by subsection 22(3).

Commissioner's report

- (2) The Commissioner shall, on behalf of the Auditor General, report annually to Parliament concerning anything that the Commissioner considers should be brought to the attention of Parliament in relation to environmental and other aspects of sustainable development, including
 - (a) the extent to which category I departments have contributed to meeting the targets set out in the Federal Sustainable Development Strategy and have met the objectives, and implemented the plans, set out in their own sustainable development strategies laid before the Houses of Parliament under section 11 of the Federal Sustainable Development Act;
 - (b) the number of petitions recorded as required by subsection 22(1), the subject-matter of the petitions and their status; and
 - (c) the exercising of the authority of the Governor in Council under subsections 11(3) and (4) of the Federal Sustainable Development Act.

Duty to examine

(3) The Commissioner shall examine the report required under subsection 7(2) of the Federal Sustainable Development Act in order to assess the fairness of the information contained in the report with respect to the progress of the federal government in implementing the Federal Sustainable Development Strategy and meeting its targets.

Duty to report

(4) The results of any assessment conducted under subsection (3) shall be included in the report referred to in subsection (2) or in the annual report, or in any of the three additional reports, referred to in subsection 7(1).

Submission and tabling of report

(5) The report required by subsection (2) shall be submitted to the Speakers of the Senate and the House of Commons and the Speakers shall lay it before their respective Houses on any of the next 15 days on which that House is sitting after the Speaker receives the report.

Appendix B Reports of the Standing Committee on Public Accounts to the House of Commons, 2010-11

The following reports have been tabled since our October 2010 Report went to print. They are available on the website of Canada's Parliament (www.parl.gc.ca).

40th Parliament, 3rd Session

Report 15—Selected Departmental Performance Reports for 2008–2009—Department of Industry, Department of Transport (Adopted by the Committee on 10 June 2010; presented to the House on 20 September 2010)

Report 16—Chapter 2, Risks of Toxic Substances, of the Fall 2009 Report of the Commissioner of the Environment and Sustainable Development (Adopted by the Committee on 17 June 2010; presented to the House on 20 September 2010)

Report 17—Chapter 1, Evaluating the Effectiveness of Programs, of the Fall 2009 Report of the Auditor General of Canada (Adopted by the Committee on 17 June 2010; presented to the House on 20 September 2010)

Report 18—Chapter 8, Strengthening Aid Effectiveness—Canadian International Development Agency, of the Fall 2009 Report of the Auditor General of Canada (Adopted by the Committee on 17 June 2010; presented to the House on 20 September 2010)

Report 19—Chapter 5, Acquiring Military Vehicles for Use in Afghanistan, of the Fall 2009 Report of the Auditor General of Canada (Adopted by the Committee on 7 October 2010; presented to the House on 25 October 2010)

Report 20—International Peer Review of the Office of the Auditor General of Canada (Adopted by the Committee on 4 November 2010; presented to the House on 24 November 2010)

Report 21 Main Estimates 2010–2011: Part III—2010-2011 Report on Plans and Priorities and 2008-2009 Departmental Performance Report of the Office of the Auditor General of Canada (Adopted by the Committee on 25 November 2010; presented to the House on 8 December 2010)

Report 22 Chapter I, Canada's Economic Action Plan, of the Fall 2010 Report of the Auditor General of Canada (Adopted by the Committee on 25 November 2010; presented to the House on 8 December 2010)

Report 23 Chapter 4. Electronic Health Records, of the Fall 2009 Report of the Auditor General of Canada, and Electronic Health Records in Canada—An Overview of Federal and Provincial Audit Reports, of the Spring 2010 Report of the Auditor General of Canada (Adopted by the Committee on 4 November 2010; presented to the House on 8 December 2010)

Report 24 C.L. que: 4, Sust dining: Development in the Northwest Territories, of the Spring 2010 Report at the Andrew Ocher dark on all (Adapted by the Communes on a December 2010, presented to the House on 2 February 2011)

Report 25—Chapter 1, Aging Information Technology Systems, of the Spring 2010 Report of the Auditor General of Canada (Adopted by the Committee on 2 December 2010; presented to the House on 2 February 2011)

Report 26—Chapter 2, Modernizing Human Resource Management, of the Spring 2010 Report of the Auditor General of Canada (Adopted by the Committee on 9 December 2010; presented to the House on 2 February 2011)

Report 27—Chapter 3, Service Delivery, of the Fall 2010 Report of the Auditor General of Canada (Adopted by the Committee on 24 March 2011; presented to the House on 25 March 2011)

Appendix C Report on the audit of the President of the Treasury Board's *Annual Report to Parliament on the Tabling of Crown Corporations' Reports 2011*

Tablings in Parliament for parent Crown corporations: Annual reports and summaries of corporate plans and budgets

Section 152 of the Financial Administration Act (the Act) requires the President of the Treasury Board to lay before each House of Parliament a report on the timing of the tabling, by appropriate ministers, of annual reports and summaries of corporate plans and of budgets of Crown corporations. This report must be tabled by 31 December.

The Act requires the Auditor General of Canada to audit the accuracy of the President of the Treasury Board's report on the timing of the tabling and to present the results in his annual report to the House of Commons.

At the time that our annual report was going to print, we were unable to include the results of the above audit, since the President of the Treasury Board's report had not yet been finalized. The auditor's report, which is required by the Act, will therefore be included in the next Report of the Auditor General of Canada to the House of Commons. It will also be appended to this year's report of the President of the Treasury Board.

Appendix D Costs of Crown corporation audits conducted by the Office of the Auditor General of Canada

The Office is required, under section 147 of the *Financial Administration Act*, to disclose its costs incurred in preparing annual audit (Exhibit D.1) and special examination reports on Crown corporations.

An annual audit report includes an opinion on a corporation's financial statements and on its compliance with specified authorities. It may also include reporting on any other matter deemed significant. A special examination determines whether a corporation's financial and management control and information systems and its management practices provide reasonable assurance that assets have been safeguarded and controlled; financial, human, and physical resources have been managed economically and efficiently; and operations have been carried out effectively.

In 2010–11, the Office completed the special examination of four Crown corporations. The costs incurred are in the following table:

Canadian Dairy Commission	\$679,967
Freshwater Fish Marketing Corporation	\$767,781
National Arts Centre Corporation	\$822,932
Telefilm Canada	\$732,825

Exhibit D.1 Cost of preparing annual audit reports for fiscal years ending on or before 31 March 2011

Crown corporation	Fiscal year ended	Cost (\$)
Atlantic Pilotage Authority	31.12.10	109,491
Atomic Energy of Canada Limited (joint audit)	31.03.11	488,501
Blue Water Bridge Authority	31.08.10	149,968
Business Development Bank of Canada (joint audit)	31.03.11	522,676
Canada Council for the Arts	31.03.11	249,403
Canada Deposit Insurance Corporation	31.03.11	189,459
Canada Development Investment Corporation (joint audit)	31.12.10	169,192
Canada Employment Insurance Financing Board	31.03.11	88,470
Canada Hibernia Holding Corporation (joint audit)	31.12.10	93,978
Canada Lands Company Limited	31.03.11	850,788
Canada Mortgage and Housing Corporation (joint audit)	31.12.10	522,749
Canada Post Corporation (joint audit)	31.12.10	705,872
Canadian Air Transport Security Authority	31.03.11	490,106
Canadian Broadcasting Corporation	31.03.11	904,937
Canadian Commercial Corporation	31.03.11	228,103
Canadian Dairy Commission	31.07.10	238,668
Canadian Museum for Human Rights	31.03.11	154,277
Canadian Museum of Civilization	31.03.11	142,013
Canadian Museum of Immigration at Pier 21	31.03.11	185,605
Canadian Museum of Nature	31.03.11	146,668
Canadian Race Relations Foundation	31.03.11	154,375
Canadian Tourism Commission	31.12.10	364,452
Defence Construction (1951) Limited	31.03.11	147,755
Enterprise Cape Breton Corporation	31.03.11	393,428
Export Development Canada	31.12.10	1,032,923
Farm Credit Canada	31.03.11	769,743
Federal Bridge Corporation Limited, The	31.03.11	155,685
First Nations Statistical Institute*	N/A	N/A
Freshwater Fish Marketing Corporation	30.04.10	235,715
Great Lakes Pilotage Authority	31.12.10	157,376
International Development Research Centre	31.03.11	207,368
Jacques Cartier and Champlain Bridges Incorporated, The	31.03.11	197,620
Laurentian Pilotage Authority	31.12.10	108,625
Marine Atlantic Inc.	31.03.11	403,298
National Arts Centre Corporation	31.08.10	319,691
National Capital Commission	31.03.11	328,395
National Gallery of Canada	31.03.11	226,671
National Museum of Science and Technology	31.03.11	173,013

[&]quot;The First Nations Statistical Institute's annual audit report for the fiscal year ended 31 March 2011 has not been started due to entity delays in completing the reports for the fiscal years ended 31 March 2008, 2009, and 2010.

Exhibit D.1 Cost of preparing annual audit reports for fiscal years ending on or before 31 March 2011 (continued)

Crown corporation	Fiscal year ended	Cost (\$)
Old Port of Montréal Corporation Inc.	31.03.11	231,738
Pacific Pilotage Authority	31.12.10	95,264
Parc Downsview Park Inc.	31.03.11	216,717
Public Sector Pension Investment Board (joint audit)	31.03.11	475,661
PPP Canada Inc. (joint audit)	31.03.11	115,682
Ridley Terminals Inc.	31.12.10	255,220
Royal Canadian Mint	31.12.10	662,113
Seaway International Bridge Corporation Ltd., The	31.03.11	96,775
Standards Council of Canada	31.03.11	105,310
Telefilm Canada	31.03.11	227,637
VIA Rail Canada Inc.	31.12.10	814,050

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